EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO ALL CASES	

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

- - -

NOVEMBER 4, 2015

- - -

Deposition of PROF. DR. MED. UWE KLINGE, held at The Quellenhoff Hotel, Monheimsallee 52, 52062 Aachen, Germany, commencing at 9:36 a.m., on the above date, before Trina B. Wellslager, Registered Professional Reporter and Notary Public.

- - -

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph|917.591.5672 fax
deps@golkow.com

APPEARANCES:

ANDERSON LAW OFFICE, LLC
BY: BENJAMIN H. ANDERSON, ESQUIRE
1360 West 9th Street
Cleveland, Ohio 44413
(216) 589-0256
ben@andersonlawoffices.net
Representing Plaintiffs

THOMAS, COMBS & SPANN, PLLC
BY: DAVID B. THOMAS, ESQUIRE
300 Summers Street
Suite 1380 (25301)
Post Office Box 3824
Charleston, West Virginia 25338
(304) 414-1800
dthomas@tcspllc.com
Representing Defendants

ALSO PRESENT:

Julie Filarski, Paralegal, Anderson Law Office
Tom Bodyziak, Technical Support
Gregory Fields, Videographer

INDEX

EXHIBITS

INDEX (Continued)

INDEX (Continued)

PLAINTIFF TRIAL EXHIBITS

I N D E X (Continued)

I N D E X (Continued)

PLAINTIFF'S EXHIBIT

(Retained by Counsel)

THE VIDEOGRAPHER: We are now on the record. My name is Gregory Fields. I'm a videographer for Golkow Technologies. Today's date is 11-4-2015. The time is 9:36 a.m.

This video deposition is being held in Aachen, Germany, in the matter of In Re: Ethicon, Inc., Pelvic Repair System, for the U.S. District Court, Southern District of West Virginia.

The deponent is Uwe Klinge. Counsel will be noted on the stenographic record. The court reporter is Trina Wellslager, and will now swear in the witness.

PROF. DR. MED. UWE KLINGE, called as a witness by the Plaintiff, having been first duly sworn, testified as follows:

THE WITNESS: I swear.

MR. THOMAS: Before we get started.

MR. ANDERSON: Sure.

MR. THOMAS: Mr. Anderson and I discussed this a little bit before the deposition. I understand that there have been a number of cross-notices filed for this deposition in different jurisdictions I can't begin to name or count.

Just for the record, I'm here for Ethicon in the Mullins' consolidated case in the Southern

District of West Virginia and the MDL that's noticed by Mr. Anderson.

MR. ANDERSON: Okay. I obviously did not cross-notice the other -- from the other jurisdictions. Whatever rules they have that apply to sworn testimony, I guess they will apply in their particular state court cases, or whatever it may be, and so we proceed and we'll see how that all plays out in the various jurisdictions.

MR. THOMAS: It's up to them.

MR. ANDERSON: Up to them, I agree.

DIRECT EXAMINATION

BY MR. ANDERSON:

Q. Okay. We ready to go? You ready, Doctor?

A. Ready.

Q. Okay. Good morning.

A. Good morning.

Q. Could you please state your name for the record?

A. My name is Dr. Uwe Klinge.

Q. Dr. Klinge, will you please tell the jury what your profession is?

A. I'm an abdominal surgeon and I'm a biomaterial science researcher.

Q. Where do you work?

A. I'm working at the University Hospital of Aachen.
Q. And that's where we are here now, Aachen, Germany?
A. Exactly.
Q. Okay. Please tell the jury a little bit about Aachen University Hospital.
A. It is a large hospital. It's a teaching hospital. It includes the medical school. It includes a huge variety of research facilities so that we can say, what we don't have, we don't need, and it includes all specialties that are necessary to make a treatment for patients on a top level.
Q. When you talk about research centers, what type of research center do you have at Aachen University Hospital?
A. There is a big number of different research centers, institutes. But the main topic for this research activities is the research of biomaterials and interactions to biology.
Q. Would those biomaterials include surgical mesh that are implanted in patients?
A. Yes.
Q. And would those biomaterials and medical devices that you have researched at Aachen University

Hospital include the PROLENE mesh that is in Ethicon's TVT line of products that we will be discussing here today?
A. Yes, it includes the Prolift, and we have been working on it for more than 20 years.
Q. Did you mean to say PROLENE?
A. PROLENE.
Q. Okay. Doctor, all your opinions here today will need to be a reasonable degree of medical and scientific certainty. Do you understand that?
A. Yes.
Q. Before we get into the issues in this case and your opinions, please tell the jury briefly about your education and training as a surgeon.
A. I started in the medical school in 1977 and finished it in 1983. In 19 -- then I started as a resident at the surgical department at the University Hospital, and I got my first certificate for general surgery in 1993. And later on, in 2004, I got the certificate for abdominal surgery.
Q. At some point in time did you stop doing surgeries and focus more full-time on your biomaterials research?
A. Yes. In 2006 I started to be full-time in research.

Q. Tell the jury a little bit about your practice of being an abdominal surgeon when you were practicing in that field.
A. Abdominal surgery includes mainly all diseases within the abdominal cavity. That means liver, gallbladder, pancreas, all diseases of the thin bowels and thick bowels, as well a lot of other diseases that can be treated by surgery.
Q. Did you treat all types of hernias when you were a practicing abdominal surgeon?
A. The repair of hernias was one of the specific topics in this department, and overall hernia is the most frequent surgical operation in Germany.
Q. Did you use synthetic surgical mesh, plastic or polypropylene mesh, in your surgical practice?
A. Yes, I did.
Q. Did you use hernia meshes in your surgical practice that were manufactured by Ethicon, the defendant in this case?
A. Yes, I did.
Q. Dr. Klinge, by this point in the trial the jury will have already heard the term PROLENE mesh a number of times. Is PROLENE old construction mesh one of the Ethicon meshes that you surgically implanted in your patients at least for some period of time?

A. Yes.
Q. Did there come a point in time where you stopped using old construction PROLENE hernia mesh for your patients?
A. Yes, we stopped using these type of meshes when we got available safer designs, safer meshes.
Q. Okay. If we could just put slide A up. It's Plaintiff's Demonstrative Exhibit 8347.
(Plaintiff's Exhibit No. 8347 was marked for identification.)
Q. What is the jury seeing on the screen here? Is this this old construction PROLENE mesh that I've been asking you questions about?
A. Yes. You see here the old construction PROLENE mesh, and this is -- meanwhile this is named or it's a typical mesh of the heavyweight, small-pore meshes.
Q. And when we hear the word pore, well, what does that refer to as the jury's looking at this photograph?
A. The pore are the holes in between the fibers.
Q. When did this PROLENE mesh originally come on the market by Ethicon?
A. It was put to the market in 19 -- around 1974.
Q. So putting together what your answer was for the jury, is it accurate to call this PROLENE mesh the 1974 old construction heavyweight PROLENE mesh with

small holes?
A. Yes.
Q. Okay. You mentioned to the jury that at some point in time you stopped using this 1974 old construction heavyweight PROLENE mesh with small holes for your patients. What types of complications were you seeing with this old construction PROLENE mesh?
A. We -- with the increased use of these meshes we saw an increased number of patients suffering from pain, restriction of the mobility of the abdominal wall in the area where we implanted this material. We saw an increased rate of wound complications. That means formation of seroma or bacterial infection. We saw increased number of recurrences at the borders of these meshes.
Q. When you talk about recurrences, just please tell the jury what that means in medical terms.
A. Recurrence means that you have a reappearance of the hernia.
Q. Okay. So the problem you went to fix comes back?
A. Yes.
Q. Okay. Well, Doctor, if you could not use or you felt you could no longer use this old construction PROLENE mesh to treat your hernia patients in the 1990s,

what did you have as an alternative material available to you back at that time?
A. At that time we only have these heavyweight, small-pore meshes available, so all or a lot of other meshes has quite similar features as this one, and therefore you have to be very restricted in the indication. And that was -- definitely that was the reason to look for safer materials.
Q. Is that when your research into biomaterials began?
A. Exactly. That was the reason to look for -- for this, and to build up a -- a research around this question.
Q. So is part of what you were doing with your research back in the 1990s into the problems with this old construction PROLENE heavyweight, small-hole mesh was you trying to find something about the design of the PROLENE mesh material that we are seeing in this photograph that may have been causing these patient injuries?
A. That was exactly the idea, to avoid these overengineered, dangerous, unsafe materials, and to look for safer alternatives for safer constructions of meshes.
Q. When you said overengineered, what does that

term mean to you or mean in the world of biomaterials science?
A. Overengineered means that it is too strong, that there is too much material to -- for the purpose it was intended to be.
Q. So as part of this research in looking at the design, what did you learn about the design, the specific design features of this old construction PROLENE material from 1974 that was causing complications in your patients and other patients?
A. We learned that this material is too strong, it has too much material. And if you can reduce the amount of the material, if you can enlarge the holes in between, that you can improve the tissue reaction and you can avoid many of the complications in the patients.
Q. As part of your research that you began in the 1990s, in looking at the biomaterial science of surgical meshes, when you started your biomaterials research, and trying to relate those to patient complications, did you work with any mesh manufacturer to try to develop safer meshes?
A. Yes.
Q. Tell the jury who you worked with.
A. For more than 10 years we worked very closely together with Ethicon as the manufacturer who provides a

lot of mesh modifications and with -- who together we planned a lot of these project and studies and made the analysis together.
Q. So were you working with Ethicon during these 10 years to try to help them develop a mesh design that would be safer than this old construction heavyweight PROLENE?
A. Definitely. That was the purpose and that was the aim we could realize together.
Q. So you were one of the mesh experts that Ethicon relied on from 1995 to 2005 to help them design and develop safer meshes?
A. That's true.
MR. THOMAS: Objection to form and leading. I'd just ask that you stop leading him so much.
Q. So were you one of the mesh experts that Ethicon relied on from 1995 to 2005 to help them design and develop safer meshes?
A. That is true.
Q. Well, why was it that Ethicon came to you and your group here in Aachen and decided that you were someone who would have expertise to help them address these complications of this old construction heavyweight PROLENE?
MR. THOMAS: Objection; form.

A. We had a big experience in Aachen for the treatment of hernia. We have incredible visibility to make research at the University Hospital, and not least, we had a good idea that we can reduce the amount of the material and then that we can, by this way, we can make it safer. So the idea, the visibility, and the experience all together leads to our joint work.

Q. After identifying these problems with the old construction heavyweight PROLENE -- well, first of all, let me ask you this question: This PROLENE mesh that we're seeing -- that the jury's seeing on the screen here, is this the identical mesh that Ethicon used and continues to use in its TVT line of products for incontinence repair?

A. That is the same structure, it is just cut into strips.

Q. Okay. When you say "strips," explain to the jury what you're talking about in terms of how they make the TVT sling out of this large piece of PROLENE mesh like this.

A. It was cut by knives in strips of one centimeter in width.

Q. Okay. So after identifying the problems with this old construction heavyweight PROLENE that is used in the TVT line of products, did any new generation mesh

products come out of that consulting arrangement between you and Ethicon?

A. Yes.

Q. Explain that to the jury, please. And if we could, let's put up Exhibit 1940, Slide 13.

(Plaintiff's Exhibit No. 1940 was marked for identification.)

A. Despite we spend a lot of time in studying this problem and despite we are writing hundreds of pages around it, the principal idea is quite simple.

MR. THOMAS: Excuse me, please. I don't mean to interrupt the witness. What I have is not the same one.

MR. ANDERSON: Off the record for a minute.

THE VIDEOGRAPHER: We are off the record. The time is 9:51 a.m.

MR. ANDERSON: So we will grab an actual copy of the document on a break, but we were going to identify Plaintiff's Exhibit 1940, which is Eth.Mesh.05479411, for the record, and that is a PowerPoint, and the purpose of using it was for demonstrative purposes in showing just the VYPRO mesh next to the PROLENE mesh.

MR. THOMAS: And do you know the date of the PowerPoint?

MR. ANDERSON: As I said, Counsel, it will be on the PowerPoint printout. So I don't know it off the top of my head.

MR. THOMAS: That's fine. Let's just proceed and we'll do the best we can.

And what's the exhibit number, Ben?

MR. ANDERSON: 1940.

THE VIDEOGRAPHER: We are back on the video record. The time is 9:55 a.m.

MR. ANDERSON:

Q. So, going back, is this a document that you reviewed and relied upon in forming your opinions here?

A. Yes.

Q. And significant to your opinions in this case?

A. Yes.

Q. So please explain to the jury, we've seen the -- the heavyweight old construction PROLENE mesh on the right from our first image. Now tell the jury what we're seeing on the left.

A. On the left you see the first prototype of the new generation of lightweight, large-pore meshes. We identified how strong the mesh should be, we identified and defined how stretchable the mesh has to be, and therefore we have been able to reduce the amount of the material in comparison to the PROLENE mesh to -- of

about 70 percent, and we have made the holes much larger than the PROLENE mesh, as large as possible. So you have then the results, a lightweight, large-pore mesh. As you can see, it is more flexible, it is stretchable, and has much larger holes than on the right side.

Q. And you mentioned prototype in your answer. But did Ethicon begin selling this VYPRO mesh, this first lightweight, large-hole mesh?

A. This was sold starting in 1997 in Germany, and two years later in the U.S. It was not -- it was more than a prototype, it was a -- yeah, it was a real product.

Q. And you said you -- you and Ethicon in developing this lightweight mesh on the left that has larger holes, you were able to expand the holes. How much larger are these holes on the left than on the right?

A. About ten times larger. The area is about ten times larger than in the right mesh.

Q. These holes that were ten times larger than the one on the right, are they that important to the -- to the mesh design, Doctor?

A. They are very important. If you're looking to what happens to the mesh when incorporated into the tissues, you will see that the VYPRO mesh, even after

incorporation still is flexible. It makes no restriction of the mobility there. You have -- when you are looking with a microscope to it you see a lot of fat cells within the holes. So no stiffness by any scar.

Q. And when you say scar, in relationship to these holes, is the size of the holes and the scarring, how does that affect patient safety once this mesh is implanted in the tissues?

A. The size of the holes is critical for the safety of the patient. When the size of the holes is too small, then the entire hole will be filled by scar tissue, and the entire area of the mesh is filled by scar tissue, and scar tissue makes it very stiff and rigid and it's not stretchable any longer. It favors shrinkage and stretch and deformation of the mesh.

Q. And do you have an opinion, to a reasonable degree of medical and scientific certainty, based upon all the work that you did during those 10 years with Ethicon in the years that you came up with in developing the safer mesh on the left, I'm sorry -- let me strike that and start over.

Do you have an opinion, Doctor, to a reasonable degree of medical and scientific certainty, as to whether or not this mesh material on the left that has 70 percent less weight and ten times larger holes will

be safer in the tissues than the old construction heavyweight PROLENE mesh on the right?

A. Yes.

MR. THOMAS: Object to the form of the question.

A. Yes, it's much safer.

(Plaintiff's Exhibit No. 1865 was marked for identification.)

Q. Showing you what we will mark as Plaintiff's Exhibit 1865, Slide 14, please. Have you reviewed and relied upon this document in coming to your opinions here today?

A. Yes.

MR. THOMAS: Counsel, do we have a date for this document?

MR. ANDERSON: Well, it's your document so we can look at the metadata to come up with the date.

MR. THOMAS: Just for our purposes today, you don't know what it is?

MR. ANDERSON: I don't know. You don't have it dated. But I'm sure that your metadata, when you produce the document, probably will have the date that it was created.

MR. THOMAS: Thank you.

BY MR. ANDERSON:

Q. Have you reviewed this slide from this PowerPoint that's up on the screen entitled, Recommended Mesh Construction?

A. Yes.

Q. And where does this slide come from?

A. It is an internal Ethicon document.

Q. Okay. And when we look at these three points from this slide, can you explain -- are these significant to your opinions?

A. Yes.

Q. Can you explain why, when we look at those three bullet points?

A. This slide clearly expressed that even in the -- even in the time period after 2006 obviously the Ethicon scientists still recognized the importance of, first, large pore sizes and, second, minimal amount of foreign body material as recommendations for a mesh construction.

And, furthermore, if you are looking to the literature they refer or they put on the leaf, you will see that there are two references coming from our work, but there are two others coming from the U.S. colleagues as well. So obviously they confirm these findings and there is no dispute about the relevance and importance of large pores and minimal amount of foreign body

materials for an adequate mesh construction.

Q. And even in these articles maybe in 2006, and this PowerPoint slide may have been created by Ethicon at some point in time after that, were the three principles under Recommended Mesh Construction known to you and as part of your work with Ethicon by the time VYPRO went on the market in 1998?

A. Definitely. These are the results of our joint work for the development of the VYPRO, and you see that it's still true in this time period up to now.

Q. I'm sorry. Now let's go to Slide 15, please.

Okay. Please tell the jury what we are seeing in this image, Dr. Klinge.

A. In the right part of the image you see again the old construction PROLENE mesh, and on the left part you see another lightweight, large-pore meshes. That is called the Ultrapro, which has been a successor of the VYPRO mesh, with pores of or holes which are again much larger than those of a PROLENE mesh.

Q. When this new generation of lightweight meshes with large holes hit the market in 1998, did other mesh manufacturers begin using this new design concept of mesh with less material and larger holes?

A. It is a well-accepted, well-established, undisputed principle that lightweight, large-pore meshes

are safer, and meanwhile almost all manufacturers provided and offered devices with this feature of material reduction and larger holes.

MR. THOMAS: Objection. Move to strike as being non-responsive as to time.

Q. And, again, my question was, after VYRPO came on the market in 1998, from that time point forward, and you understood my question to say that, correct?

A. Yes.

Q. Great.

Was the lighter-weight material with these larger holes just used by other manufacturers beginning in 1998 just for hernia?

A. No, it's used for -- for other parts of tissue repair as well.

Q. Have manufacturers used this lightweight, large-hole concept for prolapse meshes?

A. Yes.

MR. THOMAS: Objection; scope.

Q. I have no idea what that means, but let's clean it up so we don't have an objection over your answer this time.

Were these other manufacturers using lighter-weight material with larger holes for indications other than hernia, like prolapse and incontinence?

A. Yes, they did.

MR. THOMAS: Just show my objection to the other products.

Q. Did Ethicon utilize this new generation of lighter-weight mesh with larger holes in their surgical mesh products after 1998?

MR. THOMAS: Same objection as to other products and time.

A. Ethicon applied this principle of material reduction and larger holes to all their products except the old construction TVT PROLENE mesh.

Q. And when you say "all their other products," are you aware, from your review in this case and your work with Ethicon, that they use lighter-weight mesh with larger holes for its prolapse meshes for women that have pelvic organ prolapse?

A. Yes.

MR. THOMAS: Same objection.

Q. Answer?

A. Yes.

Q. And are you aware that Ethicon, through your work with them, your work as a hernia surgeon, and your work as a biomaterials science researcher for 20 years, has used the lighter-weight mesh with larger-hole design in its hernia meshes?

MR. THOMAS: Same objection.

A. Yes.

MR. THOMAS: Time and scope.

Q. Did Ethicon begin using this lighter weight, larger-hole concept, beginning with VYRPO in 1998?

A. Yes. With the development of the VYPRO and when we found these principles they became a fact, and they were applied to all new development of -- of meshes, with the exception of the TVT.

Q. So is it your understanding that despite Ethicon using the lighter weight, larger-pore concept for its prolapse meshes and its hernia meshes, that it continues to use this 1974 old construction heavyweight mesh with small holes to this day?

A. Yes.

Q. In all of its TVT line of products?

A. In all.

Q. And just so we understand what the jury's looking at on the screen here, this Ultrapro mesh on the left, when did it come on the market?

A. It came on in about 2000.

Q. And from your review and your work in this case, do you know whether or not this Ultrapro on the left was used for hernia repair by Ethicon's products?

A. Yes, it is widely used for hernia repair.

Q. And did Ethicon also employ the use of the Ultrapro mesh on the left for its prolapse repair when they developed prolapse -- pelvic organ prolapse kits?

A. It's used in the pelvic floor as well, yes.

Q. By Ethicon?

A. By Ethicon.

Q. But they never used this mesh on the left, this lighter weight, larger-hole mesh, or any of its lighter weight, larger-hole meshes, for any of its TVT incontinence in women?

MR. THOMAS: Objection; leading.

Q. Is that your answer?

A. Yes.

MR. THOMAS: Objection; leading. Asked and answered.

Q. Okay. You can take down that slide.

Did you do studies comparing the old PROLENE material that is this heavyweight, small-hole material to these newer meshes? Did you do studies?

A. We did a lot of studies where we looked to the reaction to the PROLENE mesh in comparison to other modifications, probably more than anyone else in the world.

Q. Have you published articles in the peer-reviewed medical literature that relate to the safety of

Page 30

surgical meshes either for the abdomen and the pelvic tissues?
A. Yes, we did, more than a hundred about.
Q. And when we use the words today "pelvic floor" or "pelvic tissues" in relation to mesh repair, do you use those terms to include slings for incontinence as well as meshes for pelvic organ prolapse?
A. Yes.
Q. Have you written books and book chapters that relate to the safety of surgical meshes for the abdomen and for the pelvic floor or the pelvic tissues?
A. Yes, we did.
Q. Around how many?
A. About 50.
Q. Have you been asked to speak at conferences around the world on the topic of surgical mesh complications and safer mesh design for both hernia and pelvic floor?
A. Many times, and still I am.
Q. Have you been asked by Ethicon to speak as an invited lecturer at conferences sponsored by Ethicon on the topic of safer mesh designs for both hernia and for pelvic floor repair?
A. Yes.
Q. On approximately how many occasions?

Page 31

A. Dozens.
Q. Have you been invited by Ethicon to speak to urogynecologists and urologists regarding safe design of surgical meshes for incontinence and prolapse?
A. Yes, I was.
Q. Did Ethicon ever ask you to speak about this new generation of lighter-weight meshes with larger holes at any of their conferences or anywhere in the world?
A. Many times.
Q. Where did they ask you to do that and how did they ask you to do that, please?
A. I was asked to give presentations on many conferences. We had some meetings at our university where Ethicon invited about 20 surgeons to come to the hospital where we can treat hernia patients together, and we had or I prepared some lectures in the afternoon before, and I was asked to give a report of the history of the development of the VYRPO, how it had -- how it was done, what are the findings. And this was documented in a video and this was shown at many conferences on monitor on the loop. So, yeah, I was asked to or I was able to present this lightweight concept at many conferences on invitation from Ethicon.
Q. So this DVD that Ethicon made interviewing you

Page 32

about the lightweight, large-pore concept you said was played, and I just need to make sure I understood you, on a loop, you mean at conferences?
A. On a loop. Yeah, it was shown permanently on the monitor during the conferences.
Q. Where Ethicon had a booth or Ethicon sponsored an event?
A. Yes.
Q. Okay. Have you reviewed and do you rely upon Ethicon internal documents and depositions of Ethicon witnesses for your opinions in this case?
A. Yes.
Q. Just briefly give the jury an idea of the number of pages of Ethicon internal documents and pages of Ethicon deposition testimony of their employees that you've reviewed.
A. I didn't count it, but thousands. Thousands of pages have been produced to me.
Q. With regard to this TVT line of products that has the old construction heavyweight mesh from 1974 in it for stress urinary incontinence, are you familiar with the weight, the surface area, the weave pattern and the size of those holes?
A. Yes.
Q. Okay. Is that something that you developed an

Page 33

expertise in while being a consultant to Ethicon for those 10 years, as well as researching the biomaterial science of meshes for the last 20 years?
A. Definitely it was an important part of our work.
Q. Now, Doctor, I know your -- your history is in abdominal surgery and biomaterial science research, and I know you're not a urogynecologist or a urologist. But just generally speaking, for purposes of your testimony today, how are the TVT line of products supposed to function in women?
A. The TVT is supposed to function as a ligament to take over forces, to lay flat and smooth in the tissue.
Q. In what particular condition in women is it supposed to prevent or help treat?
A. It is placed underneath the urethra to avoid any leakage.
Q. Okay. So, Doctor, at this time I'd like to talk to the jury a little bit about the way the tissue in our bodies reacts to a foreign substance like PROLENE mesh and how the mesh reacts in the tissues in the body. Is that something that you've studied over the last 20 years?
A. Extensively, yes.

Q. And at your request did we prepare some slides for the jury today to help express your opinions in that regard?
A. Yes.
Q. Do you feel that those would be helpful to you in explaining your opinions to the jury?
A. I think so.
Q. Okay. Let's go to Slide 1, PowerPoint slide entitled, Foreign Body Reaction. First of all, please tell the jury what a foreign body reaction is.
A. A foreign body reaction is the reaction of the body to -- as a defense reaction to -- to someone which is strange to the tissues.
For example, if you have a splinter in the tissues then the first reaction will be that white blood cells are forming a wall around this foreign body. Later on they form a scar capsule around this foreign body to seal it from the surrounding tissue. And, as probably everyone knows, this is related to a lot of pain, this is a lot of inflammation in this area.
This is a reaction that is -- that happens in all parts of the body, it is identical in all parts of the body. You always have this inflammation and scar reaction to a foreign body.
Q. And when you have more foreign body equals more

inflammation, what does that mean, doctor?
A. The extent of the foreign body reaction, it is very clear. It depends from the surface or at the contact area between the tissues and the foreign body. So the more foreign body, the more inflammation, the more scar tissue will have in the tissues.
Q. Doctor, one thing I want to clear up right now before we get going any further in your opinion.
Does it matter what part of the body the mesh is implanted in as to whether it will have this foreign body reaction and what that foreign body reaction will be?
A. No. It is completely independent from the area of the body. You always have the identical foreign body reaction and you always will see the more foreign body the higher the surface, the more inflammation. These are two facts that are true for every part of the body.
Q. Does it matter whether the mesh is in the pelvic tissues, the abdominal tissues, or other tissues in a woman's body, or even if it were in a man's body, as to whether or not you will have this similar foreign body reaction?
A. Not in regard to the quality of the foreign body reaction, but there are differences for the consequences to the patients. In an area as in the

pelvic floor with a lot of nerves, the risk for getting nerves entrapped into the scar, the risk for pain for these patients is higher than if you implant the mesh in an area where there are no nerves or only very small number of nerves.
Q. So if someone, an expert or another witness or even a lawyer comes into this courtroom and says the tissue reaction in the abdomen to hernia meshes doesn't apply to meshes in the pelvic tissues, what would you say to that?
MR. THOMAS: Object to the form of the question.
A. That is not true.
Q. And what is that based upon, Doctor?
A. It is based on our extensive work over 20 years, the histological analysis of human explants where we all confirmed this identical reaction to foreign bodies and this is a fact. This is undisputed, well-established, no doubt about it.
Q. Have you seen anywhere in the worldwide scientific literature or attended any scientific or medical conferences anywhere in the world or seen any credible studies that show that the problems that occur in the tissue of a person's body due to a heavyweight mesh with these small holes will only happen in hernia

cases but not happen in the pelvic tissues or other tissues of the body? Have you seen anything like that in the world?
A. No, nothing.
Q. Okay. At this point in the trial the jury would have already seen the TVT mesh sling that we have there on the slide up on the right. And I know we've been talking about foreign body reaction and inflammation.
Did I ask you to create a slide where a TVT sling rests in the body in relation to where an abdominal hernia mesh is implanted in the body?
A. Yes.
Q. Would that be helpful to explain some of your opinions here to the jury today?
A. Yes.
(Plaintiff's Exhibit No. 8333 was marked for identification.)
Q. This is Plaintiff's Exhibit Demonstrative 8333.
Doctor, please explain to the jury what they're seeing on the slide in front of them.
A. On the right side, the image on the right side there you see a cross section of the abdominal wall. That is the area where we usually place these large flat meshes to reenforce our hernia repair.

And you see that it's quite going down until the bones, and the red line is the area where usually the TVT is placed there, and you see that there is a huge overlapping of the areas. So our hernia meshes are placed in -- in the same area than - than the TVT, just we stop our dissection on top of the urethra, whereas the TVT is placed underneath the urethra.

Q. And I know that you don't place TVT slings because you're not a urogynecologist, but in terms of the image on the right, is that what you use to approximate this line in the red on the right side?

A. Yes.

Q. Okay. Let's go back to Slide 1, if we could.

Doctor, did I ask you to calculate how much mesh material there is in a TVT sling?

A. Yes.

Q. Okay. And please tell the jury how much polypropylene suture is woven in to create a TVT sling device.

A. For the total device it's about 25 meters or let me say 80 feet.

Q. And how many PROLENE sutures would it take to weave into this product to create the TVT retropubic device if we -- have you placed PROLENE sutures in the body?

A. Yes, several times I use it. Usually you cut the sutures and make a knot and you remove every -- every part of the suture that is beyond the knot, you cut it away. So definitely only one inch of the suture will stay in the body.

If you compare this to the amount of the material that is used to construct the TVT, and even if you consider that half of the implant that they implant during the implantation is cut to just the half, the material in the TVT corresponds to a thousand stitches with PROLENE.

Q. Did I ask you to bring a PROLENE suture in to show the jury today?

A. Yes.

Q. Okay. If you would just -- is this -- now this is something you've placed in patients over time?

A. It's gone. We've lost it.

Q. Here it is.

A. Yeah, yeah, yeah. Here it is.

Q. Is this something, when you're an abdominal surgeon, that you've placed in patients?

A. Yes.

Q. And please explain to the jury after you use a stitch like this or a suture how much is left in the body.

A. It's just -- it mainly depends on the size of the tissue and the skills for knotting, but it's -- usually it's less than this.

Q. And how much is that, approximately?

A. One inch.

Q. Okay. And by way of comparison, did I ask you to measure out 80 feet of polypropylene PROLENE fiber?

A. Yes.

Q. Okay. Did you bring that here today?

A. It was a pleasure.

Q. So, Doctor, what you have in your hand, now that's not what the TVT looks like when it goes in the body, correct?

A. Yes, that is correct.

Q. Okay. But if you were to take and unweave all of the fiber that's in the TVT, is that the amount that would be left?

A. Yes.

Q. And you've brought a TVT device with you today?

A. Yes.

Q. Okay. So explain why you pulled out the 80 feet of polypropylene in relation to what you're seeing there.

A. So this is the amount of the suture filament that is used to create such a device, and if you -- if

you implanted it and cut it away then at least 10 meters will stay there and this corresponds to, as I said, a thousand sutures. That means a considerably larger surface than a single suture. You have a completely different reaction, because these thousand sutures are placed in a very, very small area of the body. So you have a high density of material, and this is not comparable to the reaction to one single suture.

Q. Do you have an opinion, to a reasonable degree of medical and scientific certainty, as to whether there will be a different amount of foreign body reaction in a patient's tissues, no matter where those tissues are in the body, to this less than one inch of suture material versus 80 feet of polypropylene material as is in the TVT?

A. Yes.

Q. And what is that opinion?

A. It is a completely different reaction and it is not justified to -- to transfer the results seen at sutures to -- to the reaction to mesh materials.

Q. Does that fit within the slide that the more foreign body equals more inflammation, that with more polypropylene from the TVT you'll have more inflammation than just a one-inch stitch?

A. Definitely, yeah.

Page 42

Q. Okay. We can move that to the side, Doctor. Get that back from you.

And the suture was Plaintiff's Demonstrative 8334, and the 80 feet of fiber is Plaintiff's Exhibit 8335, and by the end we will get you the exhibit number for the TVT device.

Doctor, I want to shift gears a little bit now. But continuing on with this idea of foreign body and inflammation, I want to talk to you about the relationship between this reaction to polypropylene mesh, like the PROLENE, and a concept known as mesh contraction or mesh shrinkage. Are you familiar with those terms?

A. Yes.

Q. Just briefly tell the jury in your own words what mesh contraction or mesh shrinkage is.

A. As I told you, the -- the reaction to a foreign body is on the one hand the inflammation but on the other hand it is the formation of scar tissue around the foreign body.

The consequence or one of the normal things that happens to scar is that you have a contraction of the scar by the maturing process of the proteins in this field. So you have a reduction, a shrinkage of any scar tissue there.

Page 43

Q. So if this piece of paper is the mesh as it's in the body, can you explain to the jury what we're talking about in terms of what happens to the mesh material when there is this mesh contraction or mesh shrinkage?

A. If this is the mesh area and if this is filled completely by scar tissue, you have to consider a contraction of the scar by about 30 to 50 percent. And if a mesh is inside the scar, all together it will deform, it will -- it will reduce the area of the mesh scar compound and thereby it will push together the mesh, making these foldings, which again makes it even more stiffer.

Q. And even though that's a larger piece of paper, if that were cut into the same size strip as the TVT mesh, would it still undergo this 30 to 50 percent contraction?

A. Yes, the contraction does not depend from the size of the mesh. It happens to every -- every mesh.

Q. Have you published in the peer-reviewed literature on the subject of mesh contraction or shrinkage and the resulting complications or injuries to patients?

A. Yes.

MR. THOMAS: Objection to form.

Page 44

Q. Answer the question.

A. Yes, we did.

Q. Thank you.

Have you spoken at conferences in the last 20 years about mesh contraction of polypropylene mesh implants including the heavyweight old construction PROLENE mesh used in TVT, and spoken on and taught at conferences around the world for the last 20 years about these concepts for both hernia repair and pelvic floor repair?

A. Many, many times.

Q. Does it matter whether the mesh is in the abdomen or the pelvic tissues or anywhere else in the body whether a polypropylene mesh like PROLENE will contract or shrink after its implantation?

A. No, it does not matter where it is placed, it is just -- it is mainly related to the amount of scar that is seen around the implant.

Q. Is the amount of mesh shrinkage or mesh contraction dependent in any way on the size of these holes or the weight or amount of material that you've been explaining to the jury?

A. Yes, both of these features are critical for the shrinkage. First of all, the amount of the material, the more material the more scar, as I said

Page 45

already. And the next is, if you have very large holes as we could realize with the VYPRO or with the ULTRAPRO, then these pores are filled by fat and not any longer by scar tissue, and therefore these large pores helps to reduce the amount of shrinkage.

Q. Dr. Klinge, I would like to go through your opinions regarding any problems that can occur to women as a result of the inflammation and mesh contraction of the TVT PROLENE mesh device, okay?

A. Yes.

Q. As a hernia surgeon, did you remove contracted old construction heavyweight PROLENE mesh from patients made of the same PROLENE that's in the TVT line of products?

A. Yes, I did.

Q. And have you also removed contracted mesh from the pelvic floor?

A. Yes.

Q. Tell the jury what contracted mesh feels like when you take it out of a person's body.

A. The first impression is that you have a very dense body like concrete, it is very stiff, it is not flexible. It is deformed. Very, very hard, not soft any longer. Maybe one of the most impressive documentations of such a heavyweight shrunken mesh has

Page 46

been provided by Todd Heniford. On many conferences this was shown, and he used the explanted heavyweight mesh as a hammer knocking on our table.

So that is the appearance of these heavyweight, small-pore meshes, whereas if you are looking to the tissue reaction to the large-pore meshes, very soft is almost impossible just by feeling to identify where the mesh is located.

Q. Doctor, over the course of the last 20 years, how many explanted polypropylene surgical meshes from humans have you analyzed as part of your research and work with companies to help develop safer mesh design?

A. From human explants maybe around 500 to 600.

Q. What was the purpose of your analysis of these explanted surgical meshes?

A. The scarring is a phenomenon that we could realize in the OR without any -- any additional need for some analysis. You can feel it, you can see it. But the reason for this scarring, and in particularly the extent of the inflammation, to get a better understanding what happens there, there -- then you need the help of the microscope and the tissue analysis in particularly in those patients suffering from complications.

MR. THOMAS: Just, Ben, before you go, show my

Page 47

objection to this line of questioning. I think it's already been excluded by Judge Goodwin in his previous orders on the hernia mesh inventories and the pelvic mesh inventories for which he's excluded testimony. I just want to preserve that objection.

MR. ANDERSON: You can preserve it, but it's absolutely wrong, 100 percent. Happy to argue it with you whenever you want and however you want.

BY MR. ANDERSON:

Q. Has contraction and shrinkage of polypropylene slides been reported by Ethicon in scientific papers?

A. Yes.

(Plaintiff's Exhibit No. 1922 was marked for identification.)

Q. Handing you what has been marked as Plaintiff's Exhibit 1922. Could you put that up, please? Can you highlight the top portion? Is this a document that you recognize?

A. Yes.

Q. Is it a document you reviewed and relied upon in coming to your opinions in this case?

A. Yes, I did.

Q. If we look at this E-mail from 2006, I see some names in the from and to line. Without going through all the names, are those names that you recognize?

Page 48

A. Many of these peoples have been members of the teams that has been working with us.

Q. They're Ethicon employees?

A. Ethicon employees.

Q. You said working with us. These are the people you worked with over these years of your consulting?

A. Exactly.

Q. Okay. And the subject line is mesh and tissue contraction in animal, and then this is from Dr. Joerg Holste. Are you familiar with Dr. Holste?

A. Very, very good. We worked together for years.

Q. He said, "This was our scientific statement on mesh shrinkage. Basically small pores, heavyweight meshes induce more fibrotic, bridging tissue reaction causing more mesh shrinkage during maturing of the collagenous tissue. See my presentation about biocompatibility."

Are you in agreement with Dr. Holste from Ethicon's statement here about Ethicon's scientific statement on mesh shrinkage?

A. Totally. It reflects the result of our joint work. So it is a fact that is not longer any simple opinion.

Q. And he attaches to this E-mail an article called shrinking meshes, if you could pull that up.

Page 49

Have you reviewed and relied upon this during your work in this case?

A. Yes, I did.

Q. And who are the authors of this paper on shrinking meshes?

A. Again, members of -- of the research department from Ethicon, Germany.

Q. Okay. And if we could go to the next page, the second page of the document, please, and blow up the left side, starting with four. Stop right there, please, if you would. Let me just highlight that first paragraph.

Reading from Dr. Holste in this Ethicon statement, "For decades, meshes of mainly polypropylene, MARLEX, PROLENE and polyester, MERSILENE, have been used for hernia repair."

Blow up the third paragraph, please.

"As far as stability and elasticity are concerned, the heavyweight polyester and polypropylene meshes currently on the market are overdimensioned or not flexible enough for their intended use."

Is that significant to your opinions, those words?

A. Yes.

Q. How so?

A. You see there is no dispute that this is a fact, even within Ethicon.
Q. And overdimensioned. You mentioned the word overengineered before. Is that synonymous with this word?
A. Yes.
Q. Okay. And then let's look at that last paragraph. "As also described by the team of Professor Schumpelick in Aachen," was that part of your group here in Aachen that was working with Ethicon?
A. Yes.
Q. Okay. "The amount and structure of the implanted material is critical for the frequency and intensity of local wound complications and the extent of scar formation, which can be as severe as adverse abdominal covering stiffness."
Is that important to your opinions?
A. Yes.
Q. How so?
A. Again, it shows that it is meanwhile a well-established fact.
Q. And have you reviewed other scientific literature that discusses -- oh, strike that.
If you could please go to the end and tell us, I want to look at the date of this document, down at the

bottom. Blow up other Ethicon products. What was the date that this scientific paper on shrinking meshes was done by Ethicon?
A. It's prepared -- it's produced in 2002 and it is placed on the web page of Ethicon so that everyone can have access to it.
Q. Okay. And if you look up above in the references and just highlight on the left side one, two, three, Klinge, is Ethicon citing you in -- and on the right side -- what, five times with regard to --
A. Yes.
Q. -- their position?
Okay. Now, if we could -- let me ask you this: Have you reviewed -- strike that. New question.
Have you reviewed other scientific literature that discusses how this heavyweight old construction PROLENE in the TVT contraction shrinks?
A. Yes.
(Plaintiff's Exhibit No. 292 was marked for identification.)
(Plaintiff's Exhibit No. 8338 was marked for identification.)
Q. Showing you what we will mark as Plaintiff's PLT292. Can you put that up, please?
Okay. Also it's identified in the exhibit list

as Plaintiff's 8338. It's identified twice in the exhibit list. If you'd highlight the top part. Do you recognize this as an article that you reviewed in forming your opinions in this case?
A. Yes.
Q. Okay. Is it significant to your opinions?
A. Yes.
Q. What were the researchers doing in this study?
A. They've been looking to the width of the sling after incorporation into tissues by ultrasound, and they found for both TOT, TVT and TVT-O a reduction of the width of about 30 percent.
Q. And are those findings consistent with your published studies of the PROLENE mesh and other heavyweight meshes that you did with Ethicon concerning the amount of shrinkage that you could expect from that mesh?
A. It is in accordance to -- to the amount of shrinkage that we found.
Q. And have you seen other peer-reviewed literature regarding the contraction or mesh shrinkage of TVT PROLENE mesh?
A. Yes.
Q. Are you familiar with the Najjari article?
A. Yes, I am.

Q. That's Plaintiff's Exhibit 8388.
MR. THOMAS: I'm sorry. I thought that was the one we just had up on the board.
MR. ANDERSON: I did too. The one that was on the board was Plaintiff's PLT292.
MR. THOMAS: That's the one you gave me. I don't have 292.
MR. ANDERSON: Off the record, please.
THE VIDEOGRAPHER: We are off the record at 10:39 a.m.
(Recess from 10:39 until time 10:54 a.m.)
THE VIDEOGRAPHER: This marks the beginning of Video No. 2. We are back on the record. The time is 10:55 a.m.
BY MR. ANDERSON:
Q. And, Doctor, what were the researchers looking at in this Najjari article, 8388?
A. They also looked by ultrasound what happens to the slings when implanted into the patients, and they look to polypropylene slings on the one hand and they compared the results to PVDF slings that are slings made of another plastic material, and they confirmed that there was a shrinkage of the polypropylene slings.
Q. And was the TVT PROLENE mesh the old construction, what was used in this study?

A. Yes.
Q. And what were the results of that study?
A. They confirmed that there is in the patient that you can objectify and you can detect this shrinkage and contraction, you can see the reduction of the width of the slings by this scar contraction.
Q. Doctor, is there any way for a surgeon who is considering implanting a polypropylene mesh like TVT to know the extent of scarring and contraction that will occur over the patient's life in and around the mesh or how to control it?
A. You cannot predict the specific scar reaction of a specific patient, but you can reduce the risk. You know that if you have a huge amount of material you have a higher risk for this scar contraction.
Q. And when you say "huge amount of material," do you mean the weight of the material?
A. The weight, yeah.
Q. Okay. After you stopped using the old construction heavyweight PROLENE mesh in your patients, did you use Ethicon's new lightweight meshes with larger holes in them, this new generation of meshes that started with the VYPRO in 1998?
A. Yes, we completely changed to the use of these lightweight, large-pore meshes, and even more it was

almost -- it was impossible to make any study which uses the heavyweight mesh material.
Q. Which lightweight meshes with large holes did you use that were made by Ethicon?
A. At first we started with the VYPRO, then later on it was VYPRO II, and then mainly we used the ULTRAPRO.
Q. And ULTRAPRO, was that the second photograph that the jury saw, the one on the left with the large holes and the 70 percent less material? Is that the one that you're referring to?
A. Exactly.
Q. Okay. When you used these new generation meshes, manufactured by Ethicon, what did you notice, if anything, about your patient complications?
A. The patient complications almost disappeared. We don't have -- we have a markedly reduced number of patients suffering from pain or from local wound complications.
Q. Did you finish your answer?
A. Yes.
Q. Okay. I know that you were a consultant for over 10 years to Ethicon about safer mesh design. I want to ask you this: Did they ever come to you and ask you to help them with a safer mesh design of the TVT or

other pelvic tissue meshes?
A. We never have been asked to make a formal project for the development of pelvic floor meshes. I just remember that I have discussions with Dr. Hellhammer from Ethicon.
Q. Dr. Hellhammer from Ethicon?
A. Dr. Hellhammer from Ethicon.
Q. Okay. Tell us about those discussions, please, when did they occur and what was said?
A. She told me in about 2000 that the company planned or is in preparation of textiles for the use in the pelvic floor, and she wanted to have my opinion about it.
And I told her that when using textiles in the pelvic floor it is necessary and very important to consider what we have learned during the development of the VYPRO. You have to define how strong it is, how stretchable it is, and you have to reduce the amount of material to the least amount possible and you have to make holes that are as large as -- as large as possible. So these principles have to be considered.
Q. And from your view of the documents have you been able to determine whether or not Ethicon ever utilized these new safer lightweight, large-pore meshes for their TVT devices?

A. They're recognized in many articles that this is true, but they didn't adopt it as to configuration of the old construction PROLENE mesh.
Q. In the TVT.
A. In the TVT.
Q. And did I -- I'm sorry. Strike that. New question.
And did you help me create a slide for the jury to summarize your opinions that we've just been discussing regarding inflammation, scarring and contraction?
A. Yes.
Q. And would that be helpful in presenting your summary opinions to the jury today?
A. Yes.
(Plaintiff's Exhibit No. 8340 was marked for identification.)
Q. If we could go to Slide 6. That's Plaintiff's Demonstrative Exhibit 8340. Is this a slide that I helped you create, Doctor?
A. Yes.
Q. Okay. And if we look at that patient injury due to mesh inflammation and contraction, does this apply to the old construction heavyweight mesh in the TVT products?

A. Yes.
Q. Okay. Explain those four points briefly to the jury.
A. So it is a fact that the implantation of the mesh induces an inflammation, and this inflammation, the more material, the more inflammation, and it's a permanent inflammation. That means that the inflammation doesn't stop after one week, but it's a permanently chronic wound in the patient for decades.
In some patients there is an excessive scarring. So you have various degrees of scar formation in the different patients, and in some of them you have an excessive scar formation, and this scar formation is not only a thing that can be seen in the microscope or that you can feel, but this is strictly related to patient complications.
If the nerves are entrapped into the scar tissue, this will increase the risk for chronic pain. If you have a mesh contraction and a shrinkage with the folding of the mesh, that will cause damage to the surrounding tissue, and this will be the reason for erosions; or if you have this entrapment into the scar tissue, making it stiff and not stretchable any longer, and if this is in contact to other organs you will create organ dysfunctions. The vagina will get stiff,

the bladder will get stiff. You will create some obstruction by deforming the urethra. So a lot of these complications are strictly related to the amount of scar that is created by these implants.
So mesh inflammation and contraction are a very big concern, a critical concern for the patient safety. And the purpose of every mesh design is to reduce the inflammation and reduce the scar -- the amount of scar.
Q. Based upon your 20 years of work in the biomaterials field, including 10 years of work helping design safer meshes with Ethicon, all of your publications, your presentations at teaching conferences around the world for the last 20 years, all of the research that you have done, your review of human explants over the last 20 years and all of your work as an expert in this case, do you have an opinion, to a reasonable degree of medical and scientific certainty, as to whether the old construction, 1974 heavyweight PROLENE mesh and TVT with these small holes creates an unnecessary risk of patient injury due to the increased risk of permanent inflammation, severe scarring around the mesh, leading to chronic pain, erosions and organ dysfunction to the bladder and the vagina in some patients? Do you have an opinion?
MR. THOMAS: Object to the form of the

question.
A. Yes.
Q. And what is that opinion?
A. The old construction PROLENE mesh induces more inflammation and more scar tissue than is necessary and therefore it causes more complications than necessary.
Q. And do you consider that to be an unnecessary risk of complications to the patients as a result of the design of this TVT mesh?
A. This creates unnecessary risk and makes it unsafe.
Q. Okay, Dr. Klinge. We've talked a little bit about these holes in the mesh. I want to talk a little more specifically about them. Have you conducted research and published studies on how big these holes need to be in order to safely incorporate in the tissue?
A. Yes.
Q. Are these studies, some of them conducted with Ethicon?
A. Yes.
Q. Have you also studied and published in the peer-reviewed literature on the most important way to measure these holes to give you the best information as to whether or not a design with a particular hole size will incorporate safely into a patient's tissues?

A. Yes; we could improve the method to measure the size of the holes.
(Plaintiff's Exhibit No. 8341 was marked for identification.)
Q. And if we could just put up Slide 7, Plaintiff's Demonstrative 8341. And with regard to measuring the holes, what are we seeing here on the screen, Doctor?
A. You'll see this is the ULTRAPRO and you see there are several lines in the holes of the ULTRAPRO. And at the beginning of our research it was quite common just to take one of the line as a measurement of the size of the holes, but meanwhile we know that we have to measure it in all directions so that it is necessary to apply many or to measure many of the distances to get an idea whether the hole is big enough or whether it's too small.
Q. And you mentioned early on in your work that you -- you would use one line. By the time VYPRO and ULTRAPRO came on the market, were you and your colleagues, in conjunction with your work with Ethicon, aware of the need to measure the holes in all directions as we see in Plaintiff's Exhibit 8341?
A. Yes; but it was -- at that time it was not so critical because the VYPRO and the ULTRAPRO, they have

Page 62

holes of about three to four millimeters, so a completely different class of holes. And therefore it -- for many aspects it was sufficient to talk from large pores and small pores.

Q. So, Doctor, is it okay if a company just measures its mesh right out of the box, or as you have the TVT in front of you today, right out of the box, before it goes into the patient, before the surgeon puts it in use, is it okay for them to say, well, we measured our holes in our mesh and they're larger than one millimeter and so we're good to go, we have a safe mesh?

MR. THOMAS: Object to the form of the question.

A. If you are sure that there are not any forces that may work on the mesh, then it may be sufficient to take the textile or the size of the hole from the textile form out of the box.

Q. Would that be sort of what we're seeing in 8341, just looking at the mesh, the textile as it's made before it goes in, is that what you're talking about?

A. This is -- this is the size of the textile when taking out the textile out of the box. It may be this is true for situations where you don't have any forces applying to the meshes. But in conditions where you have to consider some forces acting on the meshes, then

Page 63

you have to look what happens to the size of the holes when these forces are applied to the device.

(Plaintiff's Exhibit No. 8349 was marked for identification.)

Q. Doctor, I'm handing you what we have marked as Plaintiff's 8349. Is this a document that you have reviewed and relied upon in this case?

A. Yes.

Q. Something that's important to your opinions?

A. Yes.

Q. What is it that we're looking at here in this document? What is this document?

A. It is an internal Ethicon document which clearly shows that they have -- they considered the problem of mesh shrinkage.

Q. And if we could go to page or Slide 6 of that presentation.

MR. THOMAS: Show my objection to the questions about this document dated February 23rd.

THE WITNESS: 2007.

MR. THOMAS: February 23rd, 2007, as not been applicable to all the plaintiffs in this case.

MR. ANDERSON: Your objection is noted.

BY MR. ANDERSON:

Q. And you've reviewed this slide, Slide 6?

Page 64

A. Yes.

Q. When we look at Slide 6 where it says "pore size," small porous meshes, is that -- another word for that small hole meshes?

A. Yes.

Q. And small hole meshes like the TVT?

A. Yes.

Q. Okay. If the holes are less than one millimeter, and one millimeter, are we talking about less than one millimeter, that measuring where the red arrows were like for instance in the ULTRAPRO?

A. Yes.

Q. Okay. Lead to fibrotic bridging and increased shrinkage. What is fibrotic bridging again?

A. Fibrotic bridging means that the entire hole is filled up by scar tissue.

Q. And then large porous meshes or large-hole meshes allow for a better and faster tissue ingrowth with less shrinkage and less contraction. Is that significant to your opinions?

A. Yes.

Q. And how so?

A. This document clearly demonstrates that the relationship between the pore size and the shrinkage is still accepted, that there is no dispute about it, that

Page 65

it is acknowledged as a fact by Ethicon.

Q. And about this faster tissue ingrowth, what's that refer to, under the large-pore mesh?

A. If the holes are large enough then the body is able to fill the holes by the local fat tissue, which is normally there in this area.

Q. Now, even though this document is dated in 2007, are these -- when were these principles acknowledged and developed as between you and Ethicon?

A. The total concept was finished in 1997, with the development of the VYPRO. Then all the facts have been on the table and all the ideas and measurements had -- had started at that time point.

Q. So even though this is dated 2007, this could have easily been a PowerPoint presentation in Ethicon in 1997; is that correct?

MR. THOMAS: Object to the form of the question.

A. Yes. The importance of this is that even 10 years later they still accepted it. It just demonstrates that there is no discussion about it, whether it's true or not. It is a fact.

Q. You indicated earlier that you had looked at over a thousand or over 500 or 600 human explants, including explants that had come from the body that were

this old construction heavyweight PROLENE mesh. Do you remember that part of your testimony?
A. Yes.
Q. Okay. As part of your research in analyzing explanted PROLENE mesh from human tissue, did you see whether the holes in those PROLENE explants were greater than one millimeter and had this fat tissue in between them or were less than one millimeter and had this fibrotic bridging as we've seen in this slide?
MR. THOMAS: Object to the form of the question.
Q. Were you able to determine that, Doctor?
A. Yes.
Q. Okay. And what did you find?
A. Almost all holes from the old construction PROLENE mesh are filled by scar tissue. It is a real exception if you see a hole where there is some -- some fat tissue in between the filament.
Q. As part of your work in this case and part of your scientific research of biomaterials, have you analyzed what happens to these mesh holes when the TVT mesh is in use and forces are placed on it either by the surgeon during the operation or after the sling is implanted in the patient and has forces placed on it? Have you analyzed that?

A. Yes.
MR. THOMAS: Objection; foundation.
Q. Well, I'm trying to lay the foundation. I'm asking if he's analyzed it. Have you analyzed that?
A. Yes.
Q. Okay. Please briefly explain for the jury what analysis or testing you were involved in.
A. We applied some forces to -- to the sling, put it into machine, and then stretched it by certain forces, and then we looked what happens to the size of the holes.
Q. Okay. As part of your review of the thousands of pages of Ethicon documents and their review of depositions, were you able to determine whether or not a surgeon who is implanting a TVT device places forces on it during implantation?
MR. THOMAS: Objection to the form of the question.
A. Yes.
Q. I'm sorry.
A. Yes.
Q. Okay. And based upon all of your scientific research, as well as your review of the documents in this case, were you able to determine whether or not once a TVT is implanted in a woman whether forces will

be placed on it in her body or otherwise known as in vivo?
A. It has to be considered that there are some -- some forces that are applied to the meshes during the implantation and after.
Q. Okay. You said that you had done some analysis of the TVT mesh regarding these forces. Briefly explain for the jury what analysis or testing you have been involved in in looking at this specific issue of how the pores in the TVT will react when stresses are placed on it.
A. We have performed an experiment where we -- where we put some stress to -- to the sling and looked to the size of the holes.
Q. Who did you collaborate with on that testing, if anyone?
A. This was done in collaboration with Professor Muhl, from The Technical University, with whom together we developed this improved analysis for the style, for the size of the holes.
Q. When did you first begin that work with Professor Muhl from The Technical Institute?
A. We started in 2005 and could finish the -- the description or the development of this method in 2007, and publish it in 2007, and later on we applied it to

mesh materials and published it again in some years later.
Q. And were you able to publish the results in the peer-reviewed literature of your testing of the TVT holes?
A. Yes, we did.
Q. Okay. Was one of those publications this year, in 2015?
A. Yes.
Q. Do those peer-reviewed publications regarding these -- strike that. New question.
And do these peer-reviewed publications cover all of the protocols, test methods, set-up and analysis of the testing that you and Professor Muhl performed?
A. Yes, I did.
Q. Regarding the test methods that you used to look at the holes and how the holes would react under forces of the TVT mesh with Professor Muhl in these peer-reviewed publications, was it scientifically possible for Ethicon or other mesh manufacturers to have done a similar analysis at the time the TVT was launched in 1998?
MR. THOMAS: Object to the form of the question.
Q. You can answer.

Page 70

A. At that time point all the testing equipment was available for -- for everyone. You had the software for image analyzing, you had the Instron machines putting some -- some forces to the meshes. So all of this was available and we did it at that time, just it was not so comfortable. You have to do it with a lot of hand, hand work.

Q. And you said Instron machines?

A. Instron machines.

Q. How long have Instron machines been around? Fifty years?

A. I would guess before World War.

(Plaintiff's Exhibit No. 776 was marked for identification.)

Q. Okay. Now, getting back to the testing that you conducted with Professor Muhl, if we could put up PLT0776. If you'd blow up the top part.

Doctor, do you recognize this as your peer-reviewed publication with Professor Muhl, and others, regarding your testing of the old construction TVT that we're here to talk about today?

A. Yes.

Q. Okay. You talked about placing forces on the TVT slings in this study. How did you determine what forces to place on the TVT during your testing?

Page 71

A. So first of all we looked to the literature, and secondly to the Ethicon documents to get a good estimate which forces are reasonably to be expected during the implantation.

Q. And as part of your review of the materials in this case, have you reviewed the expert report of Dr. Thomas Muhl regarding his testing of the TVT slings?

A. Yes.

Q. And do you rely on that report to form the basis of some of your opinions in this case?

A. Yes.

Q. Did you have input into the study that went into that report and the study protocol?

A. Yes.

Q. What was your involvement?

A. I helped to define the range of the forces.

Q. And were the results of Dr. Muhl's expert report regarding the data that was used -- strike that. New question.

Were the results of this expert report the data that was used for the published article that we're looking at here in Plaintiff's Exhibit PLT0776?

A. Yes.

(Plaintiff's Exhibit No. 8342 was marked for identification.)

Page 72

Q. Okay. If we could go to Page 8 of Professor Muhl's report, which is Plaintiff's Exhibit 8342. And if you could just blow up the top part of this.

Explain to the jury what you're seeing in these two images. And you can start with the top image.

A. First of all, these are the slings that are put into these clamps and then you have a destruction of the clamps with a controlled force there.

Q. And are these -- is the TVT mesh being tested in this?

A. This is in all of these images you have a TVT mesh. The top, the three, they are -- they are images from the Moalli publications, Moalli, a group of scientists from Pittsburgh; and underneath you see the images from Professor Muhl, and you'll see it's quite identical, the results.

The forces that are applied, on the left you have no forces, that is the crystalline form, the textile form without any force. In the middle you have a very, very low force of one newton. That means about a hundred gram, a tenth of a kilogram, and you already see this narrowing of the sling, this deformation of the sling. And on the right you see a mechanical force of 10 newton, that means approximately one kilogram, and

Page 73

you see this roping of the material, this fraying of the borders, these sharp edges of the borders. And if you compare the upper parts of the images and the lower parts, you'll see identical results.

So the PROLENE, if applied to some tension, you see -- on the one hand you see this narrowing of the holes, and on the others you see this fraying of the borders.

Q. You mentioned curling, roping and fraying with regard to this mesh design. Is that something that you have studied in your work over the last 20 years as to what curling, roping and fraying will do in the tissues?

A. Yes.

Q. And based upon that review, what reaction in the tissues does the body have to a mesh that is curled, roped and frayed like we see in these images?

A. In particularly the roping leads to a higher density of materials in the tissues there and --

Q. When you say "higher density of materials," explain to the jury what you mean in normal words.

A. That means that the fibers are coming together, that the holes are getting smaller and smaller and smaller. You have a lot of fibers very, very close together, and all of this tissue in between the fibers, it is filled completely by scar.

Page 74

Q. And do you have an opinion, to a reasonable degree of medical and scientific certainty, based upon your 20 years of work and your testing on the TVT slings, as to whether or not the appearance of this mesh at the one newton force and 10 newtons of force will be safe or unsafe in a woman's pelvic tissues?

MR. THOMAS: Object to the form of the question.

A. Yes.

Q. And what is that opinion?

A. The application of even slight forces increases the risk for producing a scarry rope that are contracting all the tissues.

Q. As part of your work in this case have you reviewed internal Ethicon documents regarding this curling, roping and fraying effect from the TVT mesh?

A. Yes.

(Plaintiff's Exhibit No. 8030 was marked for identification.)

Q. Showing you what we have marked as Plaintiff's Exhibit 8030, if you could put that up on the screen, please.

Do you recognize this as a document that you reviewed and rely upon -- and relied upon in coming to your opinions in this case?

Page 75

A. Yes.

Q. And in this Ethicon document, what is the date?

A. It is a document from 2001.

Q. And it says down below, TVT recommendations from Dr. Wang. From your review of the materials could you determine who Dr. Wang was?

A. Yes.

Q. Who was that?

A. He was a surgeon who used the TVT very, very often in his patients.

Q. Okay. And if we could go down to the minutes of the meeting regarding these recommendations from Dr. Wang and highlight the second bullet point.

"Fraying is inherent in the product based on the mesh construction."

And what is fraying again?

A. Fraying is the change in the borders.

Q. Like from the images we just saw?

A. Yes.

Q. Okay.

A. With the sharp edges.

Q. And in this Ethicon document they say when any amount of tension is applied to the mesh, fraying occurs.

Is this significant to your opinions, these two

Page 76

sentences right here, Doctor?

A. Yes.

Q. Why is that?

A. It demonstrates that this is not only a concern of Moalli or our group, but this is a concern that is raised by surgeons. They have seen it and they have seen it already in 2001, and they have reported it in 2001.

(Plaintiff's Exhibit No. 3045 was marked for identification.)

Q. Showing you what we've marked as Plaintiff's Exhibit P3045. Put that on the screen, please. If you could highlight the top part of that E-mail stream from 2013.

Is this a document that you reviewed and relied upon in coming to your opinions in this case?

A. Yes.

Q. I'm going to look at an E-mail from this string, and the subject line, TVT mesh elongation, forward by Dr. Kenny Maslow. If you could go to the next page, please.

MR. THOMAS: Show my objection to any discussion about this article in terms of time frame and foundation for this witness to talk about it.

Q. Looking at this E-mail string it says, "Hi,

Page 77

Sheelu. Can you suggest any comments on the attached photo? Dr. Maslow is our highest volume TVT user in Canada and he has apparently had this issue before."

Did I read that correctly?

A. Yes.

Q. Okay. And it asks about comments on the attached photo. Let's pull up that attached photo which is attached to this E-mail.

Have you reviewed this document?

A. Yes.

Q. Is this significant to your opinions regarding the TVT sling?

A. Yes.

MR. THOMAS: Same objection.

Q. How so?

A. It again confirms that it is not only a concern from Moalli and our group, but it's still a concern that is raised by surgeons and it is even raised in this time, so 12 years after the first warning.

(Plaintiff's Exhibit No. 4170 was marked for identification.)

Q. And if we could go back to the Moalli article, PLT4170, and go to Page 658, and highlight the -- over on the right, D and J. Do you recognize those as the two meshes that are --

MR. THOMAS: I'm sorry, do I have that one?
MR. ANDERSON: Yeah, uh-hum.
MR. THOMAS: I don't think I do.
MR. ANDERSON: Here's another copy, if you don't have one.
MR. THOMAS: Plaintiff's 4170. I think this is the first time you've given it to me.
MR. ANDERSON: Well, I apologize for that, Dave, deep from my soul.
Q. Are D and J the TVT images from this article?
A. Yes, they are.
Q. And what are we seeing in the bottom image from this Moalli testing?
A. Again you see this fraying, you see these sharp edges, and you see that the end of the fibers, when they are cut, they form these sharp edges sticking in the tissues.
Q. And is this from the same study that they did where you were comparing the Moalli images with yours and Professor Muhl's images?
A. Yes.
Q. Okay. Now, if we could just go to Page 661 of this Moalli study from the University of Pittsburgh. If you blow up the last line and then the top three lines on the next side, and put them side-by-side, if you

could, please.
It says, "The permanent elongation after C1, ten cycles between 0.5 and five newtons, or roughly 0.1 and 1.1 pounds."
And what does that relate to, the .1 and 1.1 pounds?
A. Five newtons is about one pound.
Q. Does that relate to the stretching that they were putting on?
A. The forces they put.
Q. Okay. "So the permanent elongation after C1 of the Gynecare mesh." And is that the TVT mesh?
A. Yes.
Q. "Was different from that of all the other samples tested. Gynecare samples permanently elongated by 17.5, plus or minus 4.2 percent, indicating that although very little force applied there is irreversible deformation of the TVT."
Did I read that correctly?
A. Yes.
Q. Is that significant to your opinions?
A. Yes.
Q. Briefly state why, please.
A. Because this study clearly shows that this specific device has a problem when even little force is

applied to it because then you already have a permanent deformation. That means roping, curling, and the high risk for scarry roping of the device.
Q. During your expert work in this case, have you reviewed internal Ethicon documents that would demonstrate just how much of the polypropylene fibers come off of the TVT mesh when it is stretched under anticipated conditions according to the own internal Ethicon studies?
A. Yes.
Q. And what amount of the TVT mesh is lost, based upon the internal Ethicon studies?
MR. THOMAS: Objection; foundation. Haven't seen the papers yet. Do you have them?
Q. If you could just show P1757.
MR. THOMAS: Do you have a copy for me?
MR. ANDERSON: I'm working on it, Dave.
Let's go off the record, please.
THE VIDEOGRAPHER: We are going off the record. The time is 11:31 a.m.
(Recess from time 11:31 until 11:34 a.m.)
THE VIDEOGRAPHER: We are back on the record. The time is 11:34 a.m.
(Plaintiff's Exhibit No. 1757 was marked for identification.)

BY MR. ANDERSON:
Q. Doctor, showing you what has been marked as Plaintiff's Exhibit 1757. Is this a document that you have reviewed and relied upon in coming to your opinions in this case?
A. Yes, it is.
Q. And we were just talking, before we took a little break, as to the amount of particles that Ethicon estimated would be lost from the TVT mesh. Do you remember this part of your testimony?
A. Yes.
Q. Okay. If we could go to just the top part of this and highlight it.
What year was this test done?
A. 2002.
Q. Okay. Now, if we could go over two more pages in the document, and then just highlight the right-hand side all the way down where it says, "Percent change". Actually, let's do the whole right side just so it's not quite so big.
Doctor, explain what we're seeing in the results from this internal Ethicon particle loss testing.
A. When applying forces to the mesh material you see that about 12 percent of the material is lost, that

small tiny particles are -- get off the -- off the device in these devices after having been cut mechanically.

Q. Okay. And we'll get to that in a minute. What do you mean by a mechanical-cut mesh?

A. It has been cut by large knives without any -- any further treatment.

Q. And was that the way the TVT old construction mesh was made originally by Ethicon was with this mechanical-cut knives cutting the edges of the mesh?

A. Yes.

Q. Okay. And so this is Table 1 showing 12.08 percent loss of the material of the TVT sling. Is that what you said?

A. Yes.

Q. Okay. And then if we turn to the next page, did they run a second test to determine whether or not they -- what the particle loss would be in a second test within Ethicon?

A. It's again a loss of 12 percent of the material, just some small particles getting off the -- off the device.

Q. Doctor, do you have an opinion, to a reasonable degree of medical certainty, based upon your 20 years of work in this field, and all of your other publications

and presentations, as to whether or not if the TVT sling loses 12 percent of the material, whether or not this will cause an unnecessary risk of harm to women in whom it's implanted?

MR. THOMAS: Object to the form of the question.

Q. Do you have an opinion?

A. Yes.

Q. And what's your opinion?

A. Of course it creates an unnecessary risk. If these particles get into the tissues you have an increased surface, you have an increased inflammation, you have an increased scarring. If you're losing 12 percent of the material you have an unpredictable change of the characteristics and properties of -- of the sling. So it is not acceptable.

Q. So based upon your 20 years of research in the field of biomaterials and the reaction of polypropylene mesh in the tissues, and specifically old construction PROLENE mesh that's been mechanically cut, your published literature, your teaching at conferences around the world and your review of explants, do you have an opinion, to a reasonable degree of medical and scientific certainty, as to whether this curling, roping, fraying and loss of particles of the TVT slings

that we've seen in these images and in these documents this morning will create an unnecessary risk of harm to women in whom these are implanted?

MR. THOMAS: Object to the form of the question.

A. Yes.

Q. And what is that opinion?

A. The curling, roping, particle loss, increases the risk for the patients and it is unnecessary.

Q. During your course of your review of the documents in this case, have you seen anywhere that Ethicon was recognizing a need to make design improvements to reduce this curling, roping and fraying?

A. Yes.

(Plaintiff's Exhibit No. 8343 was marked for identification.)

Q. Okay. Showing you what we'll mark as Plaintiff's Exhibit 8343.

Is this a document that you recognize?

A. Yes.

Q. And is this something that you have relied upon for your opinions in this case?

A. Yes.

Q. And were you able to determine from the documents the date of this project document?

A. It's around 2001.

Q. Let's actually pull up the -- I'm sorry. Let me --

MR. THOMAS: This says two of ten. Is there a Page 1?

MR. ANDERSON: We would like to ask you that because it's never been produced, Counsel, so please go back and ask your people. I'll give you a chance to do that.

BY MR. ANDERSON:

Q. Here's Plaintiff's Exhibit -- I'm sorry. I gave you the wrong one, Dave.

(Plaintiff's Exhibit No. 8344 was marked for identification.)

Q. Plaintiff's Exhibit 8344. Showing you that, Doctor.

Does this refresh your recollection as to the approximate time that this mesh improvement project document that we're looking at was created at Ethicon?

A. Yes, sorry, I have to correct. It's 1998.

Q. Is that the year that TVT was launched?

A. Yes.

Q. Okay. And if we just look at the product characteristics under this PROLENE mesh improvement project. And if you could just highlight 1.2, Product

Page 86

Characteristics.
"The product characteristics for the PROLENE mesh product, as defined by product management, are indicated in the following section."
Did I read that correctly?
A. Yes.
Q. Okay. Now, if we go under subjective characteristics, roll that just a little higher, 1.2.1, if you can highlight that all the way through the parenthetical. "Resistance to curling, effect of pulling in one direction of the mesh forcing a permanent curl in the structure."
Go to 1.2.3.
"The quality of the edges must be equivalent to the current PROLENE mesh."
Do you see that?
A. Yeah.
Q. And then if we go to No. 6.
"Volume of flaking, loose material which releases from the structure when the mesh is cut."
Did I read that correctly?
A. Yes.
Q. If we go to No. 7.
"The material must demonstrate a resistance to fraying, unraveling along the edges."

Page 87

Did I read that correctly?
A. Yes.
Q. And then No. 8.
"The material must not unzip, defined as the ability of the structure to fall apart without further rupture or breaking of the fibers."
Did I read that correctly?
A. (Witness nodding head.)
Q. And then No. 9.
"The material must demonstrate the ability to resume its flat shape after crumpling and folding better than the current PROLENE mesh."
Do you see that?
A. Yes.
Q. Do these highlights in this mesh improvement project back in 1998, are they significant to your opinions regarding curling, fraying, roping and particle loss of the TVT mechanical-cut mesh?
A. Yes.
Q. How so?
MR. THOMAS: Object to the form of the question.
A. You find in this list many of the points I just mentioned some minutes ago, and they have been recognized and acknowledged by Ethicon in already 1998

Page 88

as a -- as an issue for to be concerned on.
Q. Before the product was even launched on the market?
A. Before.
Q. So that was in 19 -- that document was in 1998. The Dr. Wang E-mail regarding curling, roping, fraying and particle loss was 2001, correct?
A. Yes.
Q. And then the E-mail from Dr. -- about Dr. Maslow, the user in Canada of TVT, that E-mail was in 2013?
A. Yes.
Q. So do you have an opinion as to whether or not between 1998 and 2013 Ethicon had corrected this problem of curling, roping, fraying and loss of particles along the edges of its TVT mechanical-cut mesh?
A. Yes.
MR. THOMAS: Object to the form of the question.
Q. Go ahead.
A. Yes, I have an opinion.
Q. And what's that?
A. There was no improvement in these 15 years.
(Plaintiff's Exhibit No. 3496 was marked for identification.)

Page 89

Q. Okay. Showing you what we've marked as Plaintiff's Exhibit 3496.
Is this a document that you have reviewed and relied upon for your opinions in this case?
A. Yes.
Q. Okay. If we could turn over to Paragraph 6. Highlight that, please.
It says, "Laser-cut PROLENE mesh."
Have you reviewed documents in this litigation, internal documents, regarding this laser-cut PROLENE mesh idea?
A. Yes.
Q. Okay. Explain to the jury what that was.
A. Instead of cutting the filaments with knives you can use a laser that cuts the filaments by heat. And this leads to the situation where in the line where the cutting occurs then the fibers are melted together.
So you can, by using this laser-cut procedure, you can reduce the particle loss, you can -- you make it a little bit stiffer, but you can seal a little bit the borders so that you have a smaller risk for fraying and roping when one cuts the mesh with a laser-cut procedure.
Q. Now here I see it says, "The market feedback of the laser-cut mesh compared to the guillotine cut mesh,

Page 90

or GCM."
Have you seen other documents where GCM is also known as mechanical-cut mesh or MCM?
A. Yes.
Q. Okay. And then down below it says, "There was a marked reduction in the amount of loose ends falling off."
Did I read that correctly?
A. Yes.
Q. So from your review of the documents, could you tell whether or not Ethicon decided to start using this laser=cut mesh by, as you said, welding or melting the borders of the TVT mesh material?
A. It is -- yeah.
Q. What year did they start doing that?
A. They started in 2006.
Q. Okay. And from your review of the Ethicon documents, did you determine whether by laser cutting the TVT mesh at the borders actually resolved or lessened the problems of curling, roping, fraying and particle loss?
A. Yes.
Q. Okay.
A. It really lessens the problems of particle loss and this fraying at the borders.

Page 91

Q. So when Ethicon came up with this solution of laser cutting its TVT mesh in order to reduce or prevent this particle loss, did they stop selling the mechanical-cut mesh?
A. Unfortunately not.
Q. So from your view of the documents they kept selling the laser-cut mesh and the mechanical-cut mesh at the same time?
A. At the same time.
Q. Based on all of your review in this case and 20 years of doing biomaterials research, do you have an opinion, to a reasonable degree of medical certainty, as to whether the edges or borders of this mechanical-cut TVT mesh is a safe or unsafe design?
MR. THOMAS: Object to the form of the question.
A. Yes.
Q. And what is that?
A. It is unsafer, unsafer, and obviously it is not necessary, because they already have some sort of alternative.
Q. And did you -- is it your opinion to a reasonable degree of medical certainty that the laser-cut TVT mesh is a safer alternative design than the mechanical-cut mesh?

Page 92

MR. THOMAS: Object to the form of the question.
A. Yes.
Q. And why is that?
A. It is a safer design. The laser-cut mesh is a safer design than the mechanical cut, because it has a reduced risk for roping and a decrease in the particle loss.
Q. Dr. Klinge, are you aware of other mesh manufacturers that have addressed how to design a mesh sling for stress urinary incontinence in women that will not have open borders that tend to curl, rope, fray and lose particles like the mechanical-cut TVT?
A. Yes.
MR. THOMAS: Objection. I don't think that's in his expert report, but go ahead.
MR. ANDERSON: Well, I guess we will have to look at that.
MR. THOMAS: Yes, we will. I just preserve my objection on this line of questioning.
MR. ANDERSON: You can, but I think maybe in a minute you might withdraw it, but maybe you won't.
MR. THOMAS: Maybe I will.
BY MR. ANDERSON:
(Plaintiff's Exhibit No. 4063 was marked for

Page 93

identification.)
Q. Okay. If we could go back to Plaintiff's Exhibit 4063. Oh, we've already handed this out. Is that your publication from 2015?
A. Yes.
Q. Is that something that was publicly available to everyone, including Ethicon and their lawyer sitting here next to you?
A. Yes.
Q. Was this something that was attached to your expert report?
A. Yes.
Q. Okay. Maybe we dispelled that notion.
Now, let's go to Page 5 of this, please. Pull up the top part.
What is the jury seeing in this image, Dr. Klinge?
A. You see the image of another sling with an alternative textile construction. You see there it's more square. The hole has forms of a square and you see the sealed borders just by textile construction.
Q. And was there tension applied between the sample in A and the sample in B?
A. Yes.
Q. And under force under B, what happens to the

pores?
A. You don't -- under force you don't see any significant reduction or change of the size of the holes, and you don't see any roping and curling or fraying at the edge.
Q. Do you have an opinion, Doctor, as to whether in 1998 TVT slings could have been made with a sealed border?
A. Yes.
Q. And what is that opinion?
A. A sealed border is not an invention of the last 10 years; but if you look to the socks or to the pants, sealed borders are a well-known technique for textile engineering since decades. So it's not a new invention of the past years.
MR. THOMAS: Show my objection to the line of questioning dealing with sealed borders on the TVT as being an alternative design. But go ahead.
MR. ANDERSON: I don't understand the objection, but that's okay.
Q. And when you said on the pants, are you talking about like the seam or the hem at the bottom of your pants?
A. Yes, where you don't want to have any fraying as well.

Q. Technology available in 1998?
A. Definitely.
Q. What type of mesh is this that we see here in Plaintiff's Exhibit 4063?
A. It's -- the brand name is DynaMesh. It's made of PVDF.
Q. And just briefly and slowly explain what PVDF is when you say it's made out of that. Are you saying the fibers in the mesh are made of PVDF?
A. Yes.
Q. Is that different from polypropylene like is made in the TVT device?
A. Yes. PVDF is another polymer, it's another plastic material. It is available since the middle of the '60s.
Q. And does this mesh have a brand name, this sling that's made out of this PVDF with these sealed borders in your published article, does that have a name?
A. The brand name is DynaMesh.
Q. And who is the company that makes it?
A. It's made by FEG, a company from Aachen.
Q. FEG.
And does FEG make surgical meshes for stress urinary incontinence as well as prolapse in women?

A. Yes.
Q. And is this sling that we see in Plaintiff's Exhibit 4063 made out of PVDF with the sealed borders currently available on the market?
MR. THOMAS: Object to the form of the question.
A. It's available on the market in many countries in the world.
Q. Is it available in the United States yet?
A. I don't think so.
Q. Okay. How many countries in the world is it available in?
MR. THOMAS: Object to the form of the question.
A. About --
Q. Okay. How many countries in the world is the PVDF mesh that we see in Plaintiff's PLT4063 available in, Doctor?
A. About 60, 40 to 60.
Q. How long have you known about PVDF as an alternative polymer to polypropylene for surgical meshes?
A. Exactly we started to work with PVDF in 1998. When we finished with the VYPRO development --
Q. "We" meaning you and Ethicon?

A. Yes.
Q. Okay. Go ahead.
A. When we finished our VYPRO development we wanted to make further improvements, and this can be done by reduction of the surface of the foreign body which is still there in the VYPRO.
And this could hardly be done with the use of polypropylene because polypropylene tends to be quite stiff, and therefore I asked the experts at The Technical University and at that time they indicated that PVDF is maybe the best polymer that is available at that time point, and therefore in 1998 we started a new project to create a VYPRO made of the PVDF fibers and got some -- some grants to -- to make this development.
Q. Did you have discussion -- well, first of all, was that work done in conjunction with Ethicon?
A. We started to work this together and offered the proposal to them to make a joint development of PVDF meshes. And we got some PVDF devices from Ethicon to test it, but later on Ethicon decided not to follow -- not to use PVDF as a mesh material, and therefore we focused on our work together with the FEG where we started to develop PVDF mesh materials.
Q. You said in an answer that Ethicon actually provided you with PVDF meshes for your research?

A. Yes.
Q. What year was that that they provided you with their own PVDF meshes for your research?
A. 1999.
Q. Okay. Have you studied the differences in the tissue response between polypropylene and PVDF?
A. We made our studies where we compared the PROLENE that is used in TVT when we compared this to the PVDF meshes.
(Plaintiff's Exhibit No. 0780 was marked for identification.)
Q. Showing you what's been marked as PLT0780. I'm sorry. Can I have that one?
MR. THOMAS: What's the number, please?
MR. ANDERSON: It's the one I just said. 218.
MR. THOMAS: Okay.
MR. ANDERSON: Here's what we had to do. We'll change that to PLT0780.
Q. If you could highlight the top part.
We were talking about research that you had done looking at the tissue response between polypropylene and PVDF. Can you explain what we're looking at here?
A. This is an article we published. These are the -- these are the results of our studies where we

compared the PROLENE mesh to two devices made of PVDF, one from the FEG and the other came from Ethicon.
Q. Okay. And if we could look in the middle of that. What were the results of this study, Doctor?
A. Briefly, the study confirmed that the tissue response to PVDF is much better than to polypropylene, less inflammation, less scar, less restriction of the mobility there, so in favor of PVDF.
Q. And this study was done in 2002?
A. It was published in 2002. It was done in the years 2000, 2001.
Q. And the meshes that you received, you had PROLENE, that's the heavyweight old construction mesh that's in TVT. That was your comparator?
A. Yes.
Q. And then you also received PVDF meshes that you had been receiving from Ethicon since 1998; is that correct?
A. Yes.
Q. Okay. And if we could look at the last page of that, under acknowledgement. Under the acknowledgement section of this paper from 2002, who did you receive support from?
A. Amongst Ethicon, Ethicon supported us.
Q. Okay. To your knowledge did Ethicon have a

brand name for this PVDF mesh?
A. It was called -- the brand name was PRONOVA. And as meanwhile I've seen many, many internal Ethicon documents that they made their own studies already in the '90s, all confirming that PVDF is a better material than polypropylene.
MR. THOMAS: Objection. Move to strike as non-responsive after identification of the name.
Q. Doctor, have you seen internal studies by Ethicon as to whether or not they confirm that PVDF is a better or worse material than polypropylene?
A. Yes.
MR. THOMAS: Object to the form of the question. Do we have the studies to look at?
MR. ANDERSON: We might, but I'm asking him the question for right now, since you keep objecting. I'm trying to clear up that, so let me ask my questions.
BY MR. ANDERSON:
(Plaintiff's Exhibit No. 1923 was marked for identification.)
Q. Showing you what's been marked as P1923. Highlight that top part, please.
This is an E-mail in 2007 from Dr. Dieter Engel to a John Gillespie. Are you familiar with Dr. Dieter

Engel?
A. He has been the medical director of the R & D department, research and development department, from Ethicon, Germany.
Q. Have you worked with him over the years?
A. For many years.
Q. Have you had many meetings with him?
A. Many meetings, many discussions.
Q. Was Dr. Dieter Engel one of the Ethicon representatives who was involved with your PVDF research starting back in the late '90s and early 2000s?
A. He has been our main partner in -- at Ethicon, Germany, and he was responsible for the research activities.
Q. And the research activities including PVDF and polypropylene mesh comparisons?
A. Yes.
Q. Okay. And under the first two sentences there, "Tom," he says, "Thanks for checking back and asking for my scientific perspective. There have been a number of anecdotal reports that polypropylene mesh shows some changes in the surface with time. The Aachen group," that would be you and your group here in Aachen, correct?
A. Yes.

Page 102

Q. "Who so far have collected more than a thousand explanted meshes showed examples many years back." Did I read that correctly?
A. Yes.
Q. Okay. Let's go down, if we could, please, to "What is the future?" And concludes, "Best regards, Dieter."
So with regard to this E-mail from Dieter Engel, he says, "What is the future? We will change the material of our mesh and move to PRONOVA as the future material platform for mesh starting with NG TSM. PRONOVA has a reduced foreign body reaction compared to PROLENE, as shown in several animal studies, and will improve the perceived compatibility of our mesh. Besides, PRONOVA is much less susceptible to mechanical damage as it is less stretched and a different chemical composition. It is much easier to process in the knitting machines, less quality issues."
Did I read that correctly?
A. Yes.
Q. Is this significant to your opinions and how does it relate to your work that you did with Ethicon on this PVDF project?
MR. THOMAS: Object to the form of the question.

Page 103

Q. Is this significant to your opinions, this E-mail?
A. Yes.
Q. And please relate the things that we've read in this E-mail to your experience with Ethicon.
MR. THOMAS: Object to the form of the question.
A. This E-mail clearly states that Dr. Engel recognized PVDF as a safer material in comparison to polypropylene, and this is completely in agreement to all our findings. PVDF is a safer material than polypropylene.
Q. Okay. We were talking about the -- strike that.
Doctor, based on your background, training and experience, all the studies that you've conducted, your 20 years of biomaterials research, your peer-reviewed studies on the comparison of PVDF and polypropylene in living tissue, do you have an opinion, to a reasonable degree of medical and scientific certainty, as to whether PVDF is safer as a permanent implant in human tissues than the old construction heavyweight PROLENE that's in the TVT?
MR. THOMAS: Object to the form of the question.

Page 104

Q. Do you have an opinion?
A. Yes.
Q. And what is that opinion?
A. PVDF is a safer alternative than polypropylene, which is used in the PROLENE.
Q. You told the jury earlier about consulting with Ethicon for 10 years and helping them develop safer mesh designs. Have you worked with other companies over the years, mesh manufacturers, doing the same thing, in other words, helping them with safer mesh design?
A. When the collaboration with Ethicon stopped in 2005, I continued to work with the FEG as a consultant for the development of safer meshes.
Q. Why did you decide to become a consultant to FEG?
A. From -- basically it was the employers from the FEG has been the textile engineers that has been asked by Ethicon to produce the structure of the VYPRO. So these engineers clearly knows the advantage of material reduction and large holes.
And as I told in 1998, we want to create PVDF meshes, and we have been able to work on this issue together with the FEG. And when Ethicon declined to work on PVDF meshes we still had the granted projects there, and therefore we continued to work with the FEG

Page 105

on PVDF meshes.
Q. What percentage of your professional time do you spend consulting with FEG?
A. Less than five percent.
Q. And when you worked for them, do they pay you for your time?
A. Yes.
Q. Approximately how much do they pay you for working with them per year?
A. It's about 40,000 euros a year.
Q. Do you get royalties for every PVDF mesh that's sold by FEG?
A. No.
Q. Doctor, if someone were to come in here and say that the only reason you believe that PVDF is safer than polypropylene is because you're an advisor to FEG or because you get paid some amount of money by them, what would you say to that?
A. That's ignoring the facts. We started in 1998 to focus on the development of PVDF. At that time the FEG didn't produce any meshes for the market and they -- not before 2003 they started to produce meshes for the market.
So our knowledge, our -- our knowledge that PVDF is a superior material in comparison to

Page 106

polypropylene is much older than FEG's history of producing meshes for the market.

Q. Do you speak at conferences that FEG sponsors from time to time?

A. Yes, from time to time.

Q. And in terms of the amount of conferences you speak at in a given year, approximately how many conferences are you invited to on average per year by all manufacturers?

A. About 30 invitations to give a lecture there.

Q. And approximately how many of those would you give that are sponsored by FEG or where they invited you to come?

A. That they -- conferences which are sponsored mainly by the FEG, it's only two to three.

Q. And do they pay for your travel expenses to go speak at these conferences?

A. For most of these presentations at the conferences the travel expenses are covered by either the invitation person or by a company.

Q. Has Ethicon paid you for your expenses to speak at conferences that they've sponsored in the past?

A. In a similar way as today.

Q. Is reimbursing speakers that companies invite to speak at their conferences usual and customary in

Page 107

your industry, at least for your travel expenses?

A. Yes, for the travel expenses. We don't get -- usually we don't get any honorary to make a presentation.

Q. Doctor, you've given us some opinions today about the old construction heavyweight PROLENE mesh in the TVT and various alternative designs and things like that. Before we get into any more of your opinions I want to ask you about this: Have you reviewed in the literature and in your work over the last 20 years sometimes either manufacturers or doctors refer to a procedure or device or something as a gold standard? Have you seen those words before?

A. I've seen the word "gold standard" in several publications.

Q. Okay. And, in fact, do you have a book chapter that you co-authored a few years back in which TVT -- there was a mention as to whether or not TVT was a gold standard?

A. Yes.

Q. All right. Who was your co-author in that book chapter?

A. Professor Schuessler from Lucerne, a gynecologist.

Q. And when you write articles -- I know you said

Page 108

you have over 400 publications. When you write articles are there sometimes co-authors that are from different specialties or have different professions?

A. Very, very often.

Q. Okay. And in this book chapter regarding TVT in which the words "gold standard: Are mentioned, who was responsible for writing the part about how the TVT is used and the history of TVT and whether or not it's a gold standard?

A. The words "gold standard" in this meaning from my point of view says that it is widely used, and this is an expression likely introduced by Professor Schuessler.

If you ask me for my understanding of the word of "gold standard," it is quite clear and I expressed it clearly in 2007 at a conference where I was asked to talk about the definition and the meaning and the sentence of looking for gold standard.

Q. First of all, is that 2007 presentation available online to anyone that wants to see it?

A. It's still online in the Internet, and even more it is possible to get the sound because the video is placed in the Internet.

Q. Okay. And what did you say in that 2007 presentation?

Page 109

A. I made it quite clear that the -- looking for gold standard doesn't make any sense, because we don't have the standard patients. And in particularly if you are thinking gold standard as a criteria for superior quality, that is not applicable to this.

Q. If "gold standard" means superior quality is it applicable to the TVT, in your opinion?

A. Only in the sense that it's widely used, but not as a quality, we shouldn't use it. I know that I tolerated in several texts the word "gold standard" that are introduced by others, I guess mainly in the meaning widely used, never as a criteria for quality. My personal opinion is quite clear, "gold standard," we shouldn't talk about it.

Q. Okay, Doctor. After your review of all the materials in this case regarding Ethicon's meshes for treating stress urinary incontinence, all of your publications in the scientific literature, the teaching conferences around the world at which you've spoken, the conferences at which you've spoken as an invited lecturer by Ethicon, including their invitation for you to speak at conferences for urogynecologists and urologists, your work as a hernia surgeon both implanting and explanting polypropylene meshes, including the PROLENE mesh that's used in TVT, your work

Page 110

in reviewing scientific literature and contributing to the scientific literature, all of the studies that you've done both with Ethicon and outside of your work with Ethicon, do you have an opinion, to a reasonable degree of medical and scientific certainty, as to whether the old construction heavyweight PROLENE mesh in the TVT line of products that's been mechanically cut was a safe design or an unsafe design?

MR. THOMAS: Object to the form of the question.

A. Yes.

Q. And what is that opinion, Doctor?

A. It is an unsafe design, with unnecessary risks.

Q. Have you ever seen in any of the worldwide literature or any of your review of the internal Ethicon documents or Ethicon depositions, any scientific reason for using heavyweight old construction PROLENE mesh with small holes for sling repair in SUI?

A. No, I have never seen any -- any of these reasons that indicate that there is an alternative need for the construction as it is.

Q. Doctor, did you ask me to prepare some slides for the jury just listing what you considered to be the most critical design defects in the TVT mechanical-cut mesh?

Page 111

A. Yes.

Q. If I can have that, please.

(Plaintiff's Exhibit No. 8346 was marked for identification.)

Q. Showing you Plaintiff's Demonstrative Aid 8346. Is this the slide that you asked me to help you create?

A. Yes.

Q. Okay. Tell you us what you mean by that first bullet point. Go through those four or five bullet points quickly, please.

A. I just wanted to list up again the main design defects of the PROLENE TVT mesh. And the first is the fact that it has too much material, and that makes it unsafe to use this material, to use this mesh. The holes are too small, which makes it unsafe to use this TVT mesh. You see a collapse of holes under force which makes -- was favoring this roping and curling and the particle loss, which all together makes it unsafe to use this TVT mesh. And the use of the polypropylene carries again some more risks than some possible alternatives, which makes it unsafe as well to use this TVT mesh.

(Plaintiff's Exhibit No. 8345 was marked for identification.)

Q. And if we go to Slide 9, Plaintiff's Exhibit 8345. Did you ask me to prepare a slide about safer

Page 112

alternative designs that would address all of the design defects that we just looked at in the last slide? Did you ask me to help you do that?

A. Yes.

Q. Is this that slide?

A. Yes.

Q. Explain all of these points, please, to the jury.

A. From my point of view the five disadvantages are listed in the previous image, there is no -- there shouldn't be any dispute about it. It's a fact that is well-established, it is well-accepted all over the time.

The next problem is that --

Q. When you say "all the time," over what time period?

A. Today, today. But since the development in 1997 there is no dispute about this.

Q. Okay. Go ahead.

A. However, it is necessary to think about whether it's necessary to take these risks or whether there are safer alternative designs. And if you are looking to these five features that I addressed in the previous slide, if you address the problem of material, yeah, it's possible to use less material, which would make it safer.

Page 113

Q. Okay. Let's stop you right there. What mesh products were available on the market prior to 2000 that would have less material than the old construction heavyweight TVT?

MR. THOMAS: Object to the form of the question.

A. Prior to 2000 there has been -- even within Ethicon -- there has been the VYPRO and it has been the ULTRAPRO.

Q. And --

A. Which reflects mesh materials with considerable less material.

Q. And let's go under larger holes.

A. Larger holes would make it safer for the patient because it has not this bridging effect of the scars in the holes, and therefore any use of a textile with larger holes would make it safer for the patient.

Q. What material -- mesh materials were available within Ethicon prior to 2000 that would have larger holes than the TVT?

A. Before 2000, again, Ethicon has the -- it was available for them to use the VYPRO and the ULTRAPRO.

Q. Okay.

A. As a material with larger pores.

Q. Okay. And then stable holes. Explain that to

Page 114

the jury.
A. Stable holes means that you have holes that do not collapse under forces that are stable even if you apply some forces to it.
Q. And was this design principle available to be incorporated into Ethicon's meshes prior to the year 2000?
A. It was known at that time point that you could create meshes with stable holes there.
Q. Okay. Next point.
A. The sealed borders, which make it safer. You have a lot or you have textile possibilities to seal the borders, to avoid this curling, roping and this particle loss. Within Ethicon they tried it with the laser-cut meshes.
Q. And we talked about textile designs and putting seams or hems like we do on pants and sealed borders on textiles. Was that available prior to the year 2000?
A. The knowledge was available before 2000, without any doubt.
Q. And what about the next or last point, PVDF is a safer alternative design.
A. The use of PVDF offers more options, make it safer, and of course it was available even for Ethicon to use PVDF as a plastic material for the construction

Page 115

of meshes.
So all these -- for all these features there are safer alternatives, designs possible, and they are available even before 2000.
Q. Thank you, Doctor.
From your review of all of the internal Ethicon documents and all your work in this case, have you been able to determine what the mesh is used in all of Ethicon's line of TVT products?
A. Yes.
Q. And what is that?
A. That is the PROLENE old construction TVT mesh.
Q. Okay. Is that true for the TVT Retropubic Obturator EXACT, ABBREVO and SECUR?
A. Yes.
Q. Okay. So would all of your opinions stated here today about the PROLENE mesh in the TVT retropubic be the same for all of the TVT line of products with regard to the opinions regarding design defect and safer alternative design?
MR. THOMAS: Object to the form of the question.
A. Yes, for all constructions using the old construction PROLENE mesh.
Q. Okay.

Page 116

MR. ANDERSON: That's all the questions I have at this time. Thank you, Doctor.
MR. THOMAS: Let's take a break for lunch.
THE VIDEOGRAPHER: We are off the record. The time is 12:18 p.m.
(Recess from time 12:18 until 1:05 p.m.)
THE VIDEOGRAPHER: This marks the beginning of Video No. 3. We are back on the record. The time is 1:06 p.m.
CROSS-EXAMINATION
BY MR. THOMAS:
Q. Hello, Doctor.
MR. ANDERSON: All right. Let's go. He's got his on. Let's go.
Q. Doctor, you spent a good deal of time on direct examination talking about the design and introduction of the hernia mesh VYPRO, correct?
A. Yes.
Q. And you worked with Ethicon in order to bring VYPRO to the market for hernia repair, correct?
A. We were working together to develop this.
Q. Right.
And VYPRO was the first lightweight large-pore mesh used in hernia repair, correct?
A. That is correct.

Page 117

Q. And you agree that VYPRO is not a good option for pelvic floor repair, correct?
A. To take a hernia mesh for the repair of the pelvic floor is dangerous.
Q. You agree --
A. And, therefore, it is not a good idea to take the VYPRO hernia mesh for the use in the pelvic floor. This would be a repetition of the mistake that is done with the PROLENE mesh, which is a hernia mesh that is used in the pelvic floor.
Q. But the simple answer to my question, it's your opinion that VYPRO is not a good option for pelvic floor repair, correct?
MR. ANDERSON: Objection; asked and answered. He just answered that question.
Q. Can you answer the question, sir?
MR. ANDERSON: Objection; asked and answered.
MR. THOMAS: Are you going to let him answer it?
MR. ANDERSON: You can answer it again.
A. To use VYPRO for the pelvic floor means a repetition of the primary mistake to use just a hernia mesh for some different purpose as it was done with the PROLENE mesh used for the repair in the pelvic floor.
Q. Let me direct your attention to your deposition

given on October the 22nd, 2012, Page 42. Page 42, Line 10. And you remember that you were here and I asked you questions under oath in October of 2012? Do you remember that, Dr. Klinge?

A. Yes.

Q. And you were asked the question: Is it your opinion that VYPRO was a good option for pelvic floor repair? And your answer was no. Did I read that correctly?

MR. ANDERSON: Objection. Inappropriate use of attempted cross-examination when he gave you the exact same or similar answer that he gave before.

Q. Did you give that answer in October of 2012?

A. You read this correctly.

Q. Thank you.

MR. ANDERSON: Objection. Same objection. Exactly what he said.

Q. Now, Doctor, you also talked about the development of ULTRAPRO mesh following VYPRO, correct?

A. Yes.

Q. And ULTRAPRO likewise is a lightweight large-pore mesh used in hernia repair, correct?

A. Yes.

Q. And you agree that ULTRAPRO is not an appropriate alternative design for the treatment of

stress urinary incontinence, correct?

A. The same answer as before. It is a hernia mesh that is not specifically designed for the use in the pelvic floor.

Q. Okay. So is the answer to my question that you agree that ULTRAPRO is not an appropriate design for the treatment of stress urinary incontinence?

MR. ANDERSON: Objection.

A. The answer is it is not appropriate to use a hernia mesh for the use in the pelvic floor without any reunification, adoption of the textile structure.

Q. So modification of the textile structure, is that what you said?

A. Adoption of the structure to the demands that are necessary when using these devices in the pelvic floor area.

Q. And you've not done that, have you?

MR. ANDERSON: Objection to the form.

A. I didn't do -- I didn't implant meshes for pelvic floor disorders, if you ask this one.

Q. Now, Doctor, if you go to your deposition that you gave on November 15th, 2013, on Page 529, Line 12, once again I asked you the question:

Is it your opinion that ULTRAPRO is an appropriate alternative design for the treatment of

stress urinary incontinence in women?

Answer: No.

Question: Why?

Because the structural stability is not sufficient to withstand or to preserve the big pores under -- under these conditions of biomechanics as is required for the use as a sling.

Did I read that correctly?

A. Yes.

MR. ANDERSON: Objection to an inappropriate use to attempt the cross-examination when he gave you the same answer to the deposition here that he gave you there.

BY MR. THOMAS:

Q. Now, Doctor, you advocate PVDF as a material to be used in a mesh design, correct?

MR. ANDERSON: Objection to form. Go ahead.

A. Yes.

Q. It's your opinion today that PVDF is the best polymer we have for mesh implantation in the treatment of stress urinary incontinence, correct?

A. It is the best polymer we have in the moment, yeah. I'm convinced of it.

Q. And a PVDF polymer mesh can be designed in a way that is unreasonably dangerous, correct?

A. Yes.

Q. Now, you, yourself, have conducted no studies with PVDF mesh in the human body for hernia repair, correct?

A. Please can you -- can you repeat the question?

Q. I'll withdraw the question.

You are aware of no studies that demonstrate that PVDF mesh is superior to polypropylene mesh in pelvic floor repair, correct?

MR. ANDERSON: Objection to form. Go ahead.

A. As recorded there is the study from Najjari indicating that PVDF meshes are superior to polypropylene meshes. However, it has to be addressed that clinical studies have considerable limitations to demonstrate differences when comparing materials in a clinical setting.

Q. Okay. And the Najjari study looked at the DynaMesh made by FEG, correct?

A. Yes.

Q. And the DynaMesh made by FEG out of PVDF is not sold in the United States, correct?

A. Yes.

Q. And you suggested on direct examination that Ethicon should make its own PVDF mesh for sale in the United States, correct?

Page 122

A. No.
Q. You don't.
Do you know, in order to -- is it your opinion that there can be a PVDF mesh design for the safe treatment of stress urinary incontinence?
A. Yes.
Q. Okay. And that's the alternative design that you advocate?
A. That is one alternative design. This is one safer option.
Q. Okay. And you've not set out to design the specific mesh implant for the treatment of stress urinary incontinence that would use PVDF, have you?
MR. ANDERSON: Objection to form.
A. Please, again.
MR. THOMAS: Can you read back the question, please?
(The question was read by the Reporter.)
A. I have been working on PVDF on the comparison on the reaction of the tissues to PVDF, I have been working on the safest design for meshes, but I was not involved in the specific configuration of a product.
Q. Okay. You've not yourself designed a mesh for the treatment of stress urinary incontinence which includes PVDF as the polymer, correct?

Page 123

A. That is correct. I'm not a manufacturer.
Q. Okay. And in order to bring a mesh to market you'd have to first design the mesh with the appropriate filament and the appropriate design of the mesh?
MR. ANDERSON: Objection to the form. It calls for him to be an expert in any sort of regulatory matter.
A. First of all, as we developed with the VYPRO first of all you have to define how stable it has to be, how stretchable it has to be. Then you have to decide which polymer you want to use. Then you have to decide which filament and what size you want to have. Then you're able to define the size of the holes and all together this one then, at the end of this process, you may come up with a design that likely fulfills the requirements you are to have for this specific purpose. That is the process you have to pass.
Q. And once you come up with the proposed design of the mesh you have to test that design, correct?
A. Yes.
Q. And that includes preclinical testing, correct?
A. Yes.
Q. And preclinical testing includes benchtop testing where you measure its strength and stability, correct?

Page 124

A. Yes; but, amongst many, many others. You have to see on various levels how this device behave.
Q. And then you have to do animal testing with the mesh to see how it behaves in animals, correct?
A. You have to look what happens when tissue is coming, when white cells are coming, when fibroblasts are coming, yes. This can be done only in animal experiments, but you can do studies in cell cultures as well you have to do it. So a lot of various things you should study before getting the idea that it's safe to use this in humans.
Q. And then you have to do clinical studies with the mesh as well, correct?
MR. ANDERSON: Objection to the form, and it calls for regulatory opinion. So anything that doesn't involve regulatory you can speak to or how you bring something to market. Otherwise, I'm not going to let him answer.
A. Of course if you are -- if you are producing a device for clinical use you will be happy then that if this product then really is used in the clinical studies, and you should look for the outcome to the risks for this -- for this device.
Clinical -- clinical studies with the focus on safety is how -- impossible. You need many, many

Page 125

patients. You need a very long survival follow-up, surveillance of these patients to get a good idea what really are -- what is the outcome of this specific device.
Therefore, the task of the clinical trial is to confirm that it works, and then you have to look to the outcome in some sort of registries permanently and you have to analyze the failures and you have to react to these failures.
Q. And the importance of all of this testing is to show that the new mesh that you're designing with PVDF has better results than the existing mesh, correct?
A. One other part is to show that it's better results. The other is to exclude that it has some side effects you don't want it to have.
Q. You have not designed a mesh with PVDF filament that you can show has better results than the existing polypropylene meshes on the market for the treatment of stress urinary incontinence; true?
MR. ANDERSON: Objection to form.
A. As I said, we made a lot of studies showing that PVDF material has or induce a superior tissue reaction.
Q. In animals.
A. In animals.

Q. Thank you.
A. And in humans when we are looking to explants. And we have -- when we ask our colleagues that are using these PVDF meshes, they are satisfying, they are not reporting serious complications with these materials.
Q. Your colleagues that you work with?
A. With whom we talk, have conferences.
Q. And in the United States in order for a new mesh product to be available for sale for use by physicians who want to implant that device, it has to be reviewed by the Food and Drug Administration, doesn't it?
MR. ANDERSON: Objection. Do not answer any questions that call for a regulatory opinion. He is not here, Dave, and you know it, as a regulatory expert and so he's not here to offer any opinions on the FDA and the regulatory process.
MR. THOMAS: Are you instructing him not to answer?
MR. ANDERSON: If you understand the regulatory process and what's required he can, but otherwise he can't.
MR. THOMAS: Ben, don't coach the witness.
MR. ANDERSON: Don't ask inappropriate questions, Dave.

MR. THOMAS: Now, wait a minute, Ben. The only reason I'm doing this, and you know this, is because it's been cross-noticed in a bunch of jurisdictions where the FDA evidence may come in, and I have to. I'm bound to answer it. And if you're going to instruct him not to answer, you do that.
MR. ANDERSON: You absolutely do not have to ask him that and you know that, because whether or not he's been cross-noticed in another jurisdiction he still has his expert report upon which he basis this.
And there's not one shred, not one word in his expert report, nor in any of his expert reports from the last five years that has one word about whether or not he has any knowledge about FDA regulatory process, any idea about what it takes to bring something to market. He's not a manufacturer and you know that. So I don't appreciate you trying to use --
MR. THOMAS: State your objection.
MR. ANDERSON: No, I am stating my objection. I don't appreciate you trying to use a cross-notice as a way to then ask this witness, who is an expert, and he told you, in biomaterials and hernia, and to try to ask him regulatory questions and hide behind

the, well, your friends filed these cross-notice. It's inappropriate and if you ask him another one I will tell him not to answer.
BY MR. THOMAS:
Q. Dr. Klinge, it's fair to understand that to the extent that a new mesh made from PVDF was introduced in the United States for the treatment of pelvic -- of stress urinary incontinence it would have to be reviewed and approved by the United States Food and Drug Administration?
MR. ANDERSON: Objection, and it's also objection to form. Doesn't get approved. You know that.
MR. THOMAS: It depends if it's 510(k) or if it's a new drug application or PMA. You know that.
A. I have no opinion. It's out of my field.
Q. Do you know the answer to the question whether it has to be approved by the FDA before it can be marketed in the United States?
MR. ANDERSON: Objection.
A. I think so, yeah.
Q. And you know that any new mesh using a new material for the treatment of stress urinary incontinence would have to be reviewed and either cleared or approved by the FDA prior to its use in

patients in the United States, correct?
MR. ANDERSON: Objection. You're asking him regulatory questions again, and he's not here for that, nor did I have it in his expert report, and you know that.
A. I think so, but I have no --
MR. ANDERSON: Finish your --
A. -- no detailed information about this process.
Q. In your consulting work with FEG, has FEG ever submitted an application to the United States Food and Drug Administration for the clearance to use or sell the FEG DynaMesh products in the United States?
A. So far I know, yes.
Q. You have done that.
A. They have. They have done it, but I'm not involved in this process.
Q. Is there an application pending, to your knowledge?
A. Yeah.
Q. Okay. Currently there are no PVDF meshes for the treatment of stress urinary incontinence available for sale in the United States, correct?
A. I don't have the knowledge to answer this.
Q. Now, I want to go to -- let me hand you what's been marked in a prior proceeding as DX30719. DX30719

Page 130

is the book chapter that you referred to on direct examination written in 2010 in the book Hernia Repair Sequelae?

A. That's true.

Q. And if you go to Page 719.3, the title of the chapter is Alloplastic Implants for the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse, and you're listed as one of the authors?

A. That's true.

Q. And you go to the next page, and on the right side in the second paragraph it says, "At present the gold standard in SUI surgery is the suburethral sling using either the tension-free vaginal tape, paren, TVT, or the transobturator tape, paren, TOT technique. Those two procedures do not seem to differ in terms of efficacy with TOT being advantageous because of the lower rate of bladder injuries."

That is the language that you used in the chapter that you co-authored in two 2010, correct?

A. It is correct that this is written in this text, but this text is a transcript of the oral presentation of Professor Schuessler, which later on is done by him and his colleague in a written form, and I was introduced there just to -- to deal with the textile aspects in this presentation and therefore I'm listed as

Page 131

a co-author.

Q. This was not an oral presentation this was a book chapter, isn't it?

A. All of these -- all of these chapters of this book has been oral presentations at the Suretta Factmore (phonetic) Conference sponsored only by Ethicon.

Q. Okay.

A. And there it has been an oral presentation by Professor Schuessler. And afterwards we asked every -- every speaker there to give a written excerpt of their presentation, and this was what you see here.

Q. But, Doctor, you were asked to give your comments and corrections to that book chapter, weren't you?

A. I cannot remember, but I'm sure if I had it was like this.

Q. Looks like what, that you were asked to give your comments and corrections?

A. That we have the opportunity to -- to correct the text.

Q. So you weren't given --

MR. ANDERSON: Hold on. He's not through.

MR. THOMAS: Are you finished?

MR. ANDERSON: He wasn't. He was talking. So I guess not. What else would you like to say?

Page 132

A. Yeah, usually we were asked as a co-author to look at this and to be able to make some corrections.

Q. But you were asked to give your comments and corrections to this book chapter, correct?

MR. ANDERSON: Asked and answered. You just asked the exact same thing. Go ahead, Doctor.

A. I cannot remember exactly, but I'm confident that I have been asked to -- to make some comments to this text.

Q. And this was a manuscript, wasn't it?

MR. ANDERSON: Objection; asked and answered.

Q. This was a manuscript of a book chapter, correct?

A. This is a book chapter.

Q. Right.

And you were a co-worker on this manuscript, correct?

MR. ANDERSON: Objection; asked and answered.

A. Yes.

Q. Now, you told the jury that you were a hernia surgeon up until 2006, correct?

A. Yes.

Q. And after 2006 you stopped performing hernia surgery, correct?

A. I was not only a hernia surgeon, I was an

Page 133

abdominal surgeon, and I stopped abdominal surgery in 2006, that is correct.

Q. Did you stop all surgery in 2006?

A. All surgery.

Q. And you've never implanted a TVT device.

A. No, I never did it.

Q. And you don't -- you've never made any direct measurements of the forces applied to mesh for the treatment of stress urinary incontinence, correct?

A. That is correct.

Q. And you don't know the mechanism by which TVT mesh treats stress urinary incontinence, correct?

MR. ANDERSON: Objection to form. Go ahead.

A. Yes.

Q. And you've never studied the placement of transvaginal mesh for the treatment of stress urinary incontinence, correct?

A. If you mean that I never had a look to where this mesh has been placed or where this sling was placed, that is not correct. I did have a look to figure out and to find out where this sling has been placed.

Q. But the technique of how it's done and the procedures of how it's implanted, you've not studied that, correct?

Page 134

A. "Study" in the meaning that I've seen videos, I have seen live surgery, then I've studied it. But if you believe that a study is a controlled way to analyze a problem, then it's true that we didn't make a specific study.

Q. Now, would you put up Exhibit 8333, please.

Now, the jury sees now Exhibit 8333 that you testified on direct. And the slide there originally depicts a hernia mesh implantation, correct, and you've added the TVT.

A. That is correct.

Q. So, for the jury to understand, the area that is behind the red U is hernia mesh; is that correct?

A. Maybe it's not the best image. The area is the space behind the pubic bone, and in this area there is both. There is the TVT and there is the hernia mesh. So, as I indicated, it is overlapping. It is the same area of same tissue where surgeons meet gynecologists.

Q. Doctor, that's not my point. All I want the jury to understand is that the mesh that is not the red U is hernia mesh, correct?

MR. ANDERSON: Objection; asked and answered. Go ahead.

A. The mesh that you see on the image, this is a mesh as it is used for a hernia repair, yes.

Page 135

Q. Thank you.

And the marks along the left and right side of the hernia mesh, are those sutures?

A. These are sutures, yeah.

Q. And the sutures are used to fix the hernia mesh in place, correct?

A. In --

Q. In this slide.

A. In this drawing. In this drawing. But usually it is not necessary to make any fixation of a mesh in this position.

Q. And the purpose of the creation of this slide, 8333, is to show the location where the TVT device would go, correct?

A. Yes.

Q. And the mesh contained in the TVT device is less than the mesh that's depicted in that hernia mesh in the same image, correct?

A. Just on this image. But maybe -- maybe you are you are right, but it's not the best image. Usually you are going with the mesh even five, six centimeters behind the pubic bone. And, as I indicated, we stop on top of the urethra where the TVT goes behind it.

So there is a difference of one to two centimeters, but mainly the area is quite similar, it's

Page 136

a preperitoneal space, it's the space of radials as it was called. But, you're right, it is not completely reflected in this image. There may be better ones.

Q. You know that the TVT device was invented by Professor Urmston in Sweden in the 1990s? Do you remember that from your review of documents?

A. Yeah.

Q. And the PROLENE hernia mesh was made from PROLENE polypropylene sutures?

MR. ANDERSON: Objection to form.

Q. Strike that. Let me back up again.

You know that the TVT device that you talked about at length on direct examination was made from PROLENE hernia mesh.

A. Yes.

Q. And that hernia mesh was first made in 1974, correct?

A. Yes.

Q. And the PROLENE hernia mesh was made from PROLENE polypropylene sutures. You know that?

MR. ANDERSON: Objection to form.

A. It was made from filaments made out of polypropylene.

Q. Okay.

A. It is not made that you take some sutures and

Page 137

combine it and make a mesh of it, no. So the PROLENE sutures are -- you can buy it, you can use it, but it is a completely separate thing than the textile.

Q. But the PROLENE polypropylene sutures are meant to be permanent implants in the body, correct?

MR. ANDERSON: Objection to form.

A. Yes.

Q. And PROLENE hernia mesh is meant to be a permanent implant in the body, correct?

A. Yes.

Q. And PROLENE polypropylene sutures are used in a variety of applications throughout the human body. Do you agree with that?

A. Yes.

Q. Do you know that in 1969 the United States Department of Health, Education and Welfare approved an application by Ethicon to allow it to sell its polypropylene sutures?

MR. ANDERSON: Again, objection. Trying to back door in regulatory issues with an expert who has not been designated by that. Plus, as you well know, the judge has already said that you can't bring in your PMA evidence of a suture to try to show safety of your TVT sling.

So he's not going to answer any questions that

Page 138

are outside of his expertise, and asking about FDA questions, as I said before, Counsel, is inappropriate and you well know it.

MR. THOMAS: Are you going to instruct him not to answer any questions --

MR. ANDERSON: With my qualifications to him that he's not to answer any questions that relate to regulatory or FDA because he's not been designated an expert in that area and it's not in his report, and I think it's inappropriate for you to keep asking these questions.

MR. THOMAS: All I want, Ben, if you'd let me finish my statement we'll perhaps get through this. If you're going to instruct him not to answer any questions about the FDA review, approval and regulation of polypropylene -- PROLENE polypropylene mesh, PROLENE hernia mesh and PROLENE used in TVT for the treatment of stress urinary incontinence, then that's fine. We'll be over it.

MR. ANDERSON: I'm not going to instruct him not to answer. Do you have any opinions on that? If he doesn't have any opinions on it then he can say -- you can ask him questions.

MR. THOMAS: He can tell me if he knows.

MR. ANDERSON: No, he can say I don't have any

Page 139

opinion on it.

MR. THOMAS: It's a fact, Ben, it's not an opinion.

MR. ANDERSON: But you're trying to get an opinion or else why would you ask him the questions?

BY MR. THOMAS:

Q. Can you answer the question, please?

A. I really don't know whether this decision is made on the basis for one single stitch or whether it includes a thousand stitches as would be comparable to the use of a polypropylene mesh, so therefore I cannot answer it.

Q. Do you know whether the FDA, as a part of this approval process, specifically approved the use of PROLENE polypropylene for these sutures?

MR. ANDERSON: Again, same lengthy objection. If you want to keep asking the questions all day long he's going to keep telling you it's out of his expertise and he has no opinion. Doctor?

A. I don't have sufficient information to talk about this.

Q. There have been over a billion polypropylene -- excuse me -- strike that.

There have been over a billion PROLENE polypropylene sutures used in humans since their

Page 140

introduction. Do you agree with that?

A. Yes, I agree to that.

Q. And there have been millions of hernia repairs using PROLENE polypropylene mesh. Do you agree with that?

A. Millions? I'm not sure. I don't have the data.

Q. Polypropylene is the most widely used mesh material for hernia repair, correct?

A. That is correct.

Q. And polypropylene is the favorite fiber for most mesh constructions. Do you agree with that?

A. Yes.

MR. ANDERSON: And an objection to form as to which application.

Q. And polypropylene is still appropriate for use in the pelvic floor if you have the right construction of polypropylene; true?

MR. ANDERSON: Objection; form.

A. The right construction is a -- one prerequisite that you have. The other is -- and therefore I have to point this out is if you are talking of polypropylene it has to be specified which -- which type of polypropylene.

There are polypropylenes where the manufacturer

Page 141

says it shouldn't be used in medical applications at all. So there are a huge variety of different polypropylenes. So it has to be clarified whether this polypropylene is suitable for the use in medical applications. And the second is that of course you have to have an adequate configuration, an adequate design leaving off other risks.

Q. It's true, Doctor, that your opinion is that polypropylene is not so dangerous that it should be forbidden today to use it and you're convinced it's tolerable or acceptable to use polypropylene in medicine. That's your opinion, correct?

MR. ANDERSON: Objection to the cumulative nature of the question.

A. I remember that this was a statement of one of the transcripts. May I have a look to it?

Q. Sure. I was reading from your deposition on November the 15th, 2013, Page 535.

MR. ANDERSON: 535 you say, Counsel?

MR. THOMAS: I do, Line 9 to 19.

Q. Page 9, I asked you the question:

Do you have an opinion, to a reasonable degree of scientific and medical certainty, as to whether the use of polypropylene in hernia repair is unreasonably dangerous?

Page 142

The answer you gave: The -- my present opinion is it is not so dangerous that it should be forbidden today to have to use it, and therefore I'm convinced that it is tolerable or acceptable to use polypropylene in medicine.

Did I read that correctly?

A. Yes.

MR. ANDERSON: Objection. It's a different question than you asked him.

Q. Is that a true statement today?

A. Yes.

Q. Thank you.

Now, you talked about the TVT device on direct examination and you showed it to the jury. Let me hand you a TVT device. And you've obviously handled one before, correct?

A. Yes.

Q. You've never implanted one before, correct?

A. That is correct.

Q. Now, as you're holding the device you have needles on either end. Do you know what those needles are for?

A. Yes.

Q. What are the needles for?

A. To pass the sling through the tissues.

Page 143

Q. And the mesh itself is attached to the needles, correct?

MR. ANDERSON: I'm just going to object to anything regarding clinical expertise. He's not here as a urogynecologist or a gynecologist.

Q. The mesh is attached to the needles, correct?

A. Yes.

Q. And also on the device is a plastic wrapping around the mesh, correct?

A. That is correct.

Q. And the plastic wrapping around -- okay, easy.

MR. THOMAS: Strike that. Let's go off the record for a minute.

THE VIDEOGRAPHER: We are off the record at 1:43 p.m.

(Recess from time 1:43 until 1:43 p.m.)

THE VIDEOGRAPHER: We are back on the record. The time is 1:43 p.m.

BY MR. THOMAS:

Q. Dr. Klinge, the TVT mesh device that you have in front of you has a plastic sheath around the mesh, correct?

A. That is correct.

Q. And the plastic sheath covers the mesh from one needle to the other with a break in that sheath in the middle, correct?

A. That is a correct description.

Q. And the sheath itself is affixed to the needle, correct?

A. Yes.

Q. And you know that when the TVT device is implanted in a woman that is implanted with the sheath, correct?

A. It's put in with a sheath, yeah.

Q. And the sheath is not removed until the mesh is in place, correct?

A. I'm not sure whether there is some -- some trimming afterwards, after removal of the sheath, if some surgeons are doing it. It is out of my field to -- to discuss what happens during this procedure.

Q. Okay. But you do understand that when the mesh is implanted and the needles go through the vagina and out the abdomen that what is being pulled by the needle is the mesh with the sheath on it, correct?

A. I understand from the documents from Ethicon, but they have to consider an elongation by 50 percent, they have to consider some forcing during the implantation period, and therefore that is I have to consider. I don't have own experiences whether it's really possible to do it without any tension.

Page 145

MR. THOMAS: Move to strike the answer as non-responsive.

MR. ANDERSON: I completely disagree.

MR. THOMAS: I understand you disagree, Ben.

MR. ANDERSON: You asked him the question, he gave you his answer.

BY MR. THOMAS:

Q. You understand that when the mesh is implanted and the needles go through the vagina and out the abdomen that what is being pulled by the needle is the mesh with the sheath on it, correct?

MR. ANDERSON: Objection; asked and answered.

A. I really don't understand what you are going for. If you are tearing this one, and I saw you don't like it, but then in the middle of the -- of the mesh area there is no protection of the sheath.

Q. Okay. Do you understand -- do you know how the mesh is implanted?

A. As I told you --

MR. ANDERSON: Objection. Go ahead.

A. -- I've seen it during -- on video demonstrations, during live surgery, but it is out of my expertise to discuss technical details of the procedure.

Q. You conducted a number of tests that you described where you measured the extent to which the TVT

Page 146

device would change a pore structure under different forces, correct?
A. Yes.
Q. It's true that you never tested the TVT device with the sheath on it, did you?
A. We didn't test it with the sheath on it.
Q. Thank you.
There are risks from any surgical procedures. Do you agree with that?
A. Yes.
Q. And these risks are known as complications.
A. Yes.
Q. And pain can be a complication of any surgical procedure in the pelvic floor. Do you agree with that?
A. Yes.
Q. And you've not studied the rates of complications associated with the use of mesh in the pelvic floor for the treatment of stress urinary incontinence, correct?
A. Please, can you rephrase it?
Q. What is it that you don't understand about my question so I can ask a better one?
MR. ANDERSON: He just asked you to rephrase the question. Are you going to ask him another question about why he needs to rephrase it?

Page 147

A. You want to -- you want to -- to know whether we studied the correlation between patients' complaint and the use of a mesh there?
Q. Yes.
A. This we studied extensively. All our work was done to explain the problems of the complications of the patients for pain, to look whether this is related to the textile structure, and we've published it with some explants from Professor Schuessler some years before where we could really demonstrate that it's the roping, the bridging, the shrinkage that happens after implantation of these slings.
Q. Let's go to Page 328 of your deposition on November 14, 2013.
A. What page?
Q. 328. 328, Line 14.
Are you familiar with the rates of complications associated with the use of mesh for the treatment of stress urinary incontinence?
Answer: I have read a lot of these articles but I have to admit I'm not very interested in these figures in these rates.
Did I read this correctly?
MR. ANDERSON: Objection.
A. You read this correctly.

Page 148

Q. Are you not very interested in the rates of complications?
MR. ANDERSON: Explain that.
A. I'm not interested in these data because we all know meanwhile that these studies with a hundred patients looking for a short period are not able to prove the safety or to give really an idea of how big the complication rates are. And, therefore, all of these data cannot help us to define whether it's really safe or an unsafe product.
Q. As a hernia surgeon you want to know what mesh is widely accepted in the field of abdominal wall hernia surgery, don't you?
MR. ANDERSON: Objection to the form. Go ahead.
A. Please, again, I have to -- it's a strange question.
Q. As a hernia surgery, you want to know what mesh is widely accepted in the field of abdominal wall surgery, don't you?
A. First of all, I want to use a safe mesh for the patients, and I want to be confident that it is a safe mesh. And it is a completely different aspect whether it's the most frequently used or whether it's not so often used. It may be more interesting for the

Page 149

manufacturer than -- than for me.
Q. You've stated before that it should be mentioned that the field of abdominal wall hernia repair, the use of large-pore lightweight meshes has been a standard recommended by guidelines in metaanalysis. Is that true?
MR. ANDERSON: Objection to the form.
A. It is true that the use of material reduced large-pore meshes is widely established, widely accepted and not disputed, and it is reflected in some of the guidelines which may vary depending on the guideline for what.
Q. And it's fair to understand that the use of large-pore lightweight meshes in abdominal hernia repair has become a standard recommended by guidelines and metaanalysis confirms for you that large-pore textile constructions are widely accepted in the field of abdominal wall hernia surgery, correct?
A. It is a -- one other argument that is reflected in some clinical studies and it is reflected in some metaanalysis; but it does not change and does not let or it does not change the limitations of these studies, in general.
Q. And you rely upon the European Hernia Society and the International Endoscopic Hernia Society for

Page 150

guidelines for the treatment of endoscopic hernia repair, correct, and groin hernia, correct?
A. It is one example where the material is discussed.
Q. And the guidelines to which you just referred are the guidelines in professional organizations who have experience in hernia surgery, who are familiar with the literature, and they publish as a professional organization their opinion as to the proper mesh to use in hernia application. That's true?
MR. ANDERSON: Objection; compound question. Go ahead.
A. The problem of the guidelines to state which material should be used is a very difficult one, and it cannot be answered in just one question. We have since, in the past two years, we have been working very, very hard to get a formulation of the new guidelines and it is -- it is very difficult to -- to summarize this, to bring it down to one sentence.
Q. Are you part of the groups within the hernia societies that come up with the recommendations for the proper material to use for hernia repair?
A. I'm working in some of the groups, not in all, but in some of the groups I was asked to work with them.
Q. And you do this according to protocols of the

Page 151

Oxford community on how to make guidelines?
A. That is -- these are some criteria we try to follow.
Q. And you make a --
A. It's not sufficient just to follow them.
Q. And you make a reading of the literature, correct?
A. It's a group. The entire group, it's 60 to 70 persons, colleagues, that are working together.
Q. And you all work together, read the literature, and then pass it around and comment on it, correct?
A. All the literature is -- is collected centrally so that everyone has access to all the literature, and then conclusions and statements are identified and then this is all passed and then you have a -- a conference where you can say, okay, it's disagreement or agreement. You can state how important this statement is, and usually it's a compromise. All of these formulations are a compromise done by many, many very experienced colleagues.
Q. And these are the enthusiasts who are trying to define the best therapy for a specific condition, correct?
MR. ANDERSON: Objection to form.
A. I don't have any opinion whether they are

Page 152

enthusiasts or what their driving spirit is behind it.
Q. I'm just using your word, Doctor. Have you used that word to describe them?
MR. ANDERSON: Objection.
A. I remember, maybe.
Q. Okay. You know that there are specialties of doctors who perform surgery in the pelvic floor, correct?
A. Yes.
Q. Urogynecologists perform surgery on the pelvic floor, correct?
A. Yes.
Q. Urologists perform surgery on the pelvic floor, correct?
A. Yes.
Q. Gynecologists perform surgery in the pelvic floor, correct?
A. I said that already, yes.
Q. Did I say urogynecologists? I'm sorry. I apologize.
A. The first was gynecologists.
Q. And urogynecologists perform surgery on the pelvic floor, correct?
A. I think so. We don't have this specialty in Germany.

Page 153

Q. I see.
And just like you and hernia surgery, these specialists who perform surgery in the pelvic floor meet and discuss treatments of stress urinary incontinence, correct?
A. I think so, but I don't have any specific knowledge how they discuss it.
Q. Have you ever sought to understand what the specialists in the treatment of stress urinary incontinence recommend for the treatment of that condition?
MR. ANDERSON: Objection. Outside of his expertise and not part of his expert report or opinions. With that qualification, Doctor.
A. I have read some -- some of these -- these contributions to the topic about the best treatment, but definitely finally I have to say I have no opinion which is the best procedure for treatment of what disease.
Q. Okay. So let me show you what's been marked in a prior proceeding as DX20100. And this is a document from the Food and Drug Administration dated March 27th, 2013, titled, Medical Devices, subheading, Considerations About Surgical Mesh For SUI.
Have you seen that before?
MR. ANDERSON: Objection to the use of FDA

Page 154

documents. Objection to asking this expert questions about the FDA. He's not been offered as a regulatory expert. He hasn't offered any FDA opinions in this case, nor is he going to, and it's outside of his expertise.

Q. Have you seen this document before?

A. I -- this one or a similar one maybe, but I don't have any -- any -- I do not remember precisely.

Q. The first paragraph reads: "Mesh sling procedures are currently the most common type of surgery performed to correct SUI. Based on industry estimates there were approximately 250,000 of these procedures performed in 2010. While all surgeries for SUI carry some risks it is important for you to understand the unique risks and benefits for surgical mesh slings used in SUI repair."

The next paragraph says that the FDA formed a meeting of scientific experts in September, 2011, and conducted a systematic review of the published literature from 1996 to 2011. Is that true?

MR. ANDERSON: Is what true, that the words there are on the page?

MR. THOMAS: Yes.

MR. ANDERSON: Okay. Again, I have a running objection to the use of this document.

Page 155

MR. THOMAS: Yes, you do.

MR. ANDERSON: And all of your questions to this expert are on something that's outside of his qualifications, not something we've offered him for. But if you want to waste time, go ahead.

He wants to know if that's what those words say on that piece of paper.

A. Yeah, I can follow that you read what is on the paper.

Q. Thank you.

The first bullet point says, "The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one year. Longer follow-up data is available in the literature but there are fewer of these long-term studies compared to studies with one year follow-up." Did I read that correctly?

A. You read this correctly.

Q. Do you disagree with the finding of the FDA?

MR. ANDERSON: Well, objection to the characterization that's the finding of the FDA. Go ahead.

A. My point is they are discussing a procedure. That's not -- that's not my field. My field is that the risk -- that the use of the PROLENE mesh, and there is

Page 156

nothing where they've wrote that you have to use a heavyweight small-pore mesh to get these results. If you use it 250,000 times a year I think you have to be very, very sure that there is no risk.

Q. No risk at all?

MR. ANDERSON: Hold on. Let him finish his question.

A. That the lowest risk that is feasible, that you can't avoid any risk. Because the risk that some of the patients can get harmful complications is very, very high. And in all this document it is not written that you -- that it's necessary to use a heavyweight small-pore mesh.

Q. Let me show you what's been marked in a prior proceeding as DX20207.

MR. ANDERSON: Same objection. He's not here as a urogyn. expert.

Q. Did you consider the physician statement of the American Urological Association in your opinions in this case?

MR. ANDERSON: Objection; asked and answered.

A. I'll have to read it.

Q. Did you consider Exhibit 20207 in the formulation of your opinions in this case?

MR. ANDERSON: Same objection to the document

Page 157

and to the questions.

A. This document again discusses the value of the sling procedure, and I don't have any opinion to it. It does not discuss whether it is necessary to use a heavyweight small-pore meshes to get these results.

Q. I have a bunch of these statements, Doctor. You're aware there are a number of organizations of doctors around the world who have endorsed midurethral slings for the treatment of stress urinary incontinence. Is that fair?

MR. ANDERSON: Objection. Same objections. Outside of his expertise and not why he's here to be called as an expert. Hasn't offered that as part of his opinions nor in his report. Go ahead.

A. If you state that you have a huge heap of these documents I cannot comment on it.

Q. And your point is, at least in the statements that you've seen so far, is there's nothing in there that says that you must use what you've described as a heavyweight small-pore mesh; is that correct?

A. I don't know what do you have in your documents. The documents you showed just recently, they didn't give any -- any -- any data or any facts that show that it is necessary to apply a high-risk device for the use as a sling.

Q. What are the incremental risks caused by the TVT device over your alternative design?

MR. ANDERSON: Objection to the form. No idea what that means. Go ahead, Doctor. Objection to the form of the question. If you can answer it.

A. This is written in the report. This is summarized in the last figure of the direct investigations. And so these are the five main risk factors, disadvantages making the device unsafe.

Q. Okay. How do you make it safer?

A. That is the other figure or the safer alternative design. So if you are looking -- you have to accept that more material means more foreign body reaction. So you have to reduce the amount of material to the least amount possible. That is one point.

The second point is that you have to keep the distance between the filament as large as possible to allow fat to be placed in the holes. This will make it safer.

The third point is, you have to consider that you have to apply some tension to this, either within the body or during the implantation. If applying tension to it the risk is that the collapse go down and that the collapse or that the pores and the holes collapse, then you have an increased -- increased risk

for scar formation.

The next is that when you have -- don't have closed borders you have an increased risk for curling, roping, particles. All of these three increases the risk for the patient, increases the inflammation, and increases the scarring.

Q. How much?

MR. ANDERSON: Let him finish.

Q. I'm sorry.

MR. ANDERSON: Go ahead.

A. And the third point is that with the polypropylene you have a more intense inflammatory reaction, the foreign body granuloma, the reaction of the tissue is more intense than it would be with the PVDF. So all of these five points contribute to the increased risk.

Q. How much increased risk are we talking about?

MR. ANDERSON: Objecti8on to form.

A. First of all, it is impossible to play one issue against the other to say this is more important or not. It is a fact that all these five features increases the risks.

If you want to know whether this increased risk is responsible for the patient's complication, it depends to the patients where you are looking to. If

you just look to patients with chronic pain and you know it was a good experienced surgeon, it was a consultant of Ethicon who knew very well how to do it, it was a good patient, then it is very likely that it is material related and that you can improve the results with a safer material.

So in this group of patients the chance is very, very high that you can improve the results with a better material, but you don't have any other chance. You cannot change the patient, whether the doctor really knows how to do it, you cannot improve it furthermore.

Q. What are the chances -- strike that.

I have a low battery here.

THE VIDEOGRAPHER: We are off the record. The time is 2:10 p.m.

(Recess from time 2:10 until 2:13 p.m.)

THE VIDEOGRAPHER: We are back on the record. The time is 2:13 p.m.

(Klinge Exhibit No. 1 was marked for identification.)

BY MR. THOMAS:

Q. Dr. Klinge, I'm going to hand you what's been marked as Klinge Trial Deposition Exhibit No. 1, and represent to you that this is a document prepared by several authors, including two experts who are

testifying for the plaintiffs in this case. You've seen this document before, haven't you?

A. Maybe. I'm not sure.

Q. Turn to Page 5 of that document, please. Are you on Page 5?

A. Yes.

Q. Page 5, Table 3, it says, "Complications of RP slings." That's retropubic slings. Do you see that?

A. Yes.

Q. And you know retropubic slings are the class of which TVT is a part. You know that, don't you?

A. Yes.

Q. Now, Table 3 is complications of retropubic slings, correct?

A. Yes.

Q. Now, do you have any reason to disagree with the rates of complications that are presented here?

A. I cannot comment on it.

Q. Okay. That's fine.

I want to use one as an example for my question. Down under longer-term complications it says, "Refractory pain greater than eight weeks." It says that 1.8 percent of patients experience pain greater than six weeks. Do you see that?

MR. ANDERSON: Objection to the form.

Page 162

A. I see it.
Q. What would the design defects -- strike that.
What would the design changes that you recommend do to the rate of pain that's reported in Klinge Trial Deposition No. 1?
MR. ANDERSON: Objection to form.
A. To explain it to you, when we changed from the heavyweight small-pore meshes to the use of large-pore lightweight meshes, we didn't see this number of patients with chronic pain after mesh implantation. We never saw patients with a stiff abdomen.
So if you have good patients, if you have a proper technique, then hopefully you can avoid all of these patients with chronic pain by improving the device.
Q. So you're --
A. And it is not reflective and it is not grasped by this number which is a sum up of all studies looking to various time points, various definitions.
So our experience, and this is confirmed by many, many others, when you are reducing the amount of material, when you are using large-pore mesh materials --
MR. ANDERSON: Losing or using?
A. Using. You don't see these patients in the

Page 163

number as you see it with the other materials. And even if it's one, it is happy. The patient is happy and you will be happy there.
Q. Is it your testimony that by making the design changes that you are here that you're going to reduce this number of 1.8 percent in the patient population for chronic pain?
MR. ANDERSON: Objection. Go ahead.
A. You cannot take this number of 1.3 -- 8 percent as a real for everything for a specific patient. But you're right. If you can reduce this 1.8 to zero just by using a safer design, then it will be great. I would be satisfied then. But I don't believe that this 1.8 is the true incidence.
Q. I see. You believe this number's wrong.
MR. ANDERSON: Objection. That's not what he said.
A. As I said, I don't believe that this is a true incidence.
Q. Okay. And what I'm trying to understand, Doctor, are you able to quantify the change in the risk of complications from the five items that you listed on Exhibit 8346? You can't quantify the change, can you?
MR. ANDERSON: Objection; asked and answered, multiple ways. Answer it again, Doctor.

Page 164

A. As I tried to explain, it of course depends from the group of patients you are looking at.
In the best cases you can avoid completely this complication by using a safer design, as we have seen in our patients.
Q. Now, Doctor, when you first published your review paper on the lightweight and large porous mesh concept for hernia repair, that was in 2005? Do you recall that?
A. Yes.
(Klinge Exhibit No. 2 was marked for identification.)
Q. I'm going to mark as Klinge Trial Exhibit No. 2 your article, The Lightweight and Large Porous Mesh Concept For Hernia Repair.
And the title, as you've talked on direct examination, suggests that you're trying to get mesh that's of lighter weight that you implant in the body, correct?
MR. ANDERSON: Objection to form.
A. The title includes both lightweight and large porous, and it is not so helpful to isolate this or to reduce it into one.
Q. As a matter of fact, the state of your research today is that weight of the mesh alone is not an

Page 165

indicator of its safety; true?
A. If you just stick on the weight and nothing else, then this is true. It is a ridiculous discussion.
Q. And, in fact, newer studies in the area of hernia repair show there is no difference in the quality of life for people using lighter weight mesh for hernia repair as opposed to heavier weight mesh for hernia repair, correct?
MR. ANDERSON: Objection to form.
A. There is no way or I know there are many studies or there are some studies that does not find any significance; but the absence of significance is not similar to the proof of the equality or similarity. All these studies are underpowered to demonstrate that there are -- is really a similar or equal result. They all express the underpowered design of the clinical study, so they are not able to detect differences.
(Klinge Exhibit No. 3 was marked for identification.)
Q. Let me show you what I've marked as Klinge Trial Exhibit No. 3. Klinge Trial Exhibit No. 3 is a study from 2012 in the Annals of Surgery. You recognize that journal as a reputable journal?
MR. ANDERSON: Object to the journal. Object that it's outside of his expertise. But go ahead,

Doctor.
A. I know this journal.
Q. And you know the authors of this study, don't you?
A. I know some of them or only -- only Todd Heniford.
Q. Okay.
A. We talked about him already.
Q. Okay. Oh, by the way, when you talked about Dr. Heniford banging that piece of mesh on the table, that wasn't a PROLENE hernia mesh, was it?
A. It was a heavyweight small-pore mesh.
Q. It was a Kugel mesh by Bard, correct?
A. Yes.
Q. It wasn't a PROLENE hernia mesh, correct?
A. It was a heavyweight small-pore mesh.
Q. But it wasn't PROLENE mesh.
A. It was a heavyweight small-pore mesh. And we all know that it's --
MR. THOMAS: Strike that.
MR. ANDERSON: Do you want him to answer the question?
MR. THOMAS: He already has answered the question. I don't want him to go on and on. We'll be here all day.

MR. ANDERSON: It's your question so if we're here all day it's your fault.
BY MR. THOMAS:
Q. You never answered my question, I don't think.
It's true that the mesh that Dr. Heniford banged on the table is a Kugel mesh for hernia repair manufactured by Bard. You know that to be true?
A. With similar characteristics than the PROLENE mesh.
Q. Doctor, can you answer my question yes or no, please? Let me ask it again.
It's true that the mesh that Dr. Heniford banged on the table is a Kugel mesh by Bard used for hernia repair; true?
MR. ANDERSON: Asked and answered. He answered earlier it was the Kugel mesh.
Q. I couldn't find the answer. Let me ask it again.
A. Yes.
Q. It's true, Doctor, that the mesh that Dr. Heniford banged on the table that you discussed on direct examination is a Kugel mesh used for hernia repair manufactured by Bard.
A. Yes.
Q. Now, Dr. Heniford's one of the authors in this

study, correct?
A. He's one of the authors, yeah.
Q. And in this study the authors are looking at 710 hernia repairs, correct?
A. That is correct.
Q. And down in conclusions it describes this as the largest prospective quality of life study comparing these kinds of hernia repairs, correct?
A. That's in the text.
Q. And you're familiar with the International Hernia Mesh Registry, aren't you?
A. I'm not an expert for this -- for the contents of this registry.
Q. But you're familiar with the registry, aren't you?
A. I know that there is a registry, but I'm not familiar with the details of the variables, whether they are -- whether they are suitable to reflect the reality. I don't know how they control the correctness and the completeness of the data sets. So, therefore, I don't know the details, how the registry is providing the data.
Q. Okay. If you look on the right side down at the bottom it says that there are more than 30 centers in the United States, Canada, Europe and Australia that

contribute to the registry. Did you know that?
A. I'm reading it as you're --
Q. Okay. Have you seen this study before?
A. Some years before, but I don't remember the details any longer.
Q. And you recognize the -- the evaluation for quality of life that they're talking about in the -- in the title of the study. Do you know what it means to evaluate the quality of life for patients?
A. There are several attempts to objectify the quality of life after an operation, usually done by several questioners.
Q. And you're familiar with the Carolinas Comfort Score?
A. It's one of the tools that can be used.
Q. Okay. Have you ever used that tool to measure the quality of life in hernia repairs?
A. No, we didn't use it.
Q. Okay. If you go to -- and this study looked at 710 repairs over about four years, correct?
A. There is six at 12 months, one month, one month. One, six and 12 months I read. I didn't find --
Q. I'm sorry.
A. -- four years.
Q. Yeah, I was looking at the title under methods

Page 170

that they gathered the database from September, 2007, to July of 2011. That's what I was looking at.
A. But it's completely different to a study with a follow-up of four years.
Q. I see what you mean. So this is up to a one year follow-up for these patients?
A. In some of the patients I don't find the figures how many of them has a complete follow-up.
Q. Okay. If you'd turn to Page 721, the next to the last page.
A. 721.
Q. You see on the left side beginning in multivariant analysis. Do you see that?
A. Yeah.
Q. These authors looking at 710 repairs conclude that in multivariate analysis mesh weight had no effect on pain, activity limitation, mesh sensation or overall symptoms in the present study. The effect of mesh weight on quality of life had been studied more extensively in the inguinal hernia literature, where lightweight mesh is often associated with improved quality of life. In a recent small, comparative study of OVHR with light and heavyweight mesh, no difference was seen in quality of life, using SF-36, that's another quality of life questionnaire, right?

Page 171

A. That's correct.
Q. With long-term follow-up. The results of this study confirm these findings.
So this study found that the weight of the mesh had no effect on pain, activity limitation, mesh sensation or overall symptoms, correct?
MR. ANDERSON: Objection to the form.
A. This is a perfect -- this is a perfect example that --
Q. Could you answer my question first and then explain? This study found that in multivariate analysis mesh weight had no effect on pain, activity limitation, mesh sensation or overall symptoms in the present study.
A. That's how it's written here.
Q. Did they find that?
MR. ANDERSON: He said that's in fact how it's written there.
Q. I'm sorry. I didn't understand him to say that. I'm sorry. I apologize.
MR. ANDERSON: Give your full answer.
A. It's written that they cannot find it because to find that there are similar results with a heavyweight and the lightweight you need more patients, we need less subgroups. So there is an insufficient setting to detect any differences. And the absence, as

Page 172

I tried to explain to you, the absence of a difference does not mean that the equality or similarity is proven, no, and therefore they can state we didn't identify any difference. We couldn't isolate. We couldn't show any difference, but that's it. It is not suitable and it's not justified to conclude mesh weight had no effect on pain. That is scientifically not justified.
Q. What that says is they couldn't detect a difference between the light and the heavyweight mesh, correct?
MR. ANDERSON: Objection; asked and answered. He gave you his full answer. We stand by his answer.
Q. Can you answer it?
MR. ANDERSON: He did answer it.
A. I don't have further comment on it.
(Klinge Exhibit No. 4 was marked for identification.)
Q. Let me hand you what's been marked as Klinge Trial Exhibit No. 4.
MR. ANDERSON: Thank you.
Q. Klinge Trial Exhibit No. 4 is an article by William Cobb and others about mesh repair of complex incisional hernias, correct?
A. It is correct.

Page 173

Q. And Dr. Cobb was one of the authors, along with Dr. Heniford, in an article similar to yours about lightweight and large-pore mesh repair, correct?
A. Yes.
Q. And in this study over a seven-year period they looked at 255 retromuscular mesh repairs of midline incisional defects, correct?
A. Yes.
Q. And in evaluating polypropylene meshes they determined that recurrence was more likely with lightweight mesh, at 22.9 percent, as compared to mid-weight mesh at 10.6 percent; is that correct?
A. They find it.
Q. Okay. And this study was published in 2015, correct?
MR. ANDERSON: Objection to the document.
A. That is correct.
Q. And as a result of this study, Dr. Cobb, one of the authors of a study similar to yours in 2005, has stopped using lightweight mesh for the repair of these kinds of hernias, correct?
A. As a result he favors the use of mid-weight mesh materials. He doesn't want to go to heavyweight small-pore meshes, but he is favoring the use of material reduced mid-weight meshes.

Page 174

I totally agree that there are some patients with huge defects where you need some stronger meshes. But even he tells you there is no need for the heavyweight meshes, but he is satisfied with the mid-weight meshes.

Q. The answer to my question is he stopped using lightweight meshes for the repair of this type of hernia, correct?

A. As I told you, in favor of the mid-weight meshes.

Q. The answer is yes?

A. Yes.

MR. ANDERSON: He answered your question. He answered your question.

Q. Now, you, yourself, have never studied the extent to which TVT mesh contracts after implantation, have you?

A. We have studied extensively the shrinkage of the PROLENE mesh used for TVT.

Q. Doctor, my question was very specific. You have never studied the extent to which tissue surrounding TVT mesh contracts after implantation.

MR. ANDERSON: A, it's a different question; B, he even answered that.

A. We extensively studied the extent of shrinkage

Page 175

and scar formation around the PROLENE mesh.

Q. Would you go to Page 447, please, of your deposition on November the 15th, 2013, Line 12.

Have you ever conducted a study to determine the extent to which the tissue surrounding mesh after implantation for the treatment of stress urinary incontinence?

Your answer: We did a lot of these studies with PROLENE, with MARLEX, which is the mesh used for the treatment of -- I'm talking -- I'm sorry, but we didn't make specific analysis which reflects the treatment with a sling and the pelvic.

Is that answer correct? That's the answer you gave at your deposition, correct?

A. You read it correctly.

Q. And you have not done any specific analysis with respect to contraction of mesh after implantation for the treatment of stress urinary incontinence, correct?

A. We did make an analysis to investigate the effect of this material to the tissues. We did not do a specific study looking to the implanted sling in human -- in women.

Q. And you don't know the rate of complications from contracture or shrinker -- strike that.

Page 176

You do not know the rate of complications from contracture or shrinkage in the placement of mesh for the treatment of stress urinary incontinence, correct?

A. I don't know anyone who is knowing the complete rate of complications with a long follow-up of 20 years or 30 years, so there is no way to give you a detailed data involving that. Therefore, I don't know it.

THE VIDEOGRAPHER: We are off the record. The time is 2:37 p.m.

(Recess from 2:37 until 2:42 p.m.)

THE VIDEOGRAPHER: We are back on the record. The time is 2:42 p.m.

(Klinge Exhibit No. 5 was marked for identification.)

BY MR. THOMAS:

Q. Doctor, I've handed you what's been marked as Klinge Trial Exhibit No. 5, and it's a study by Nilsson, et al., Seventeen Years' Follow-up of the Tension-Free vaginal Tape Procedure for Female Stress Urinary Incontinence. Have you seen this before?

A. I had a look to it.

Q. If you look on the right side it says, talking about the material used, "The tape material used in the TVT operation was from the beginning a Type 1 mesh, characterized by a monofilament, polypropylene, large

Page 177

pore size structure." Do you see that?

A. I see it.

Q. The authors here characterize the TVT device as having a large-pore structure, correct?

A. They named it as a large pore size structure and referred to the classification of Amid, which is just focusing on the risk for infection, and it is not comparable to the modern definition of large pore that was developed with VYPRO in 1997.

MR. THOMAS: Move to strike everything after he said, "They named it as a large-pore structure."

Q. If you turn to the next to the last page -- strike that.

This is -- this study started as 90 women and they were followed prospectively for 17 years, correct?

A. So it's in the text, yeah.

Q. And 68 percent of the women were available for follow-up. Do you see that?

A. Sixty-eight. Sixty-eight. Where is it?

Q. Under results. Sixty-eight percent of the potentially assessable women were evaluated either by a clinic visit or by a telephone interview.

A. Seventy-eight.

Q. Seventy-eight, thank you.

A. Here it's 78 percent.

Page 178

Q. Yes, I read that incorrectly. Thank you.
MR. ANDERSON: 78 percent.
A. Yes.
Q. Seventy-eight percent of the potentially assessable women were evaluated either by a clinic visit or by a telephone interview. It continues. Over 90 percent of the women were objectively continent, 87 percent were subjectively cured or significantly improved. If you turn to the next to the last page of the study on the right side --
A. That's the bottom?
MR. ANDERSON: Next to the last page.
Q. Next to the last page, on the right side, it begins -- keep going. Keep going. That one.
A. That one.
Q. See the paragraph beginning, important observation?
A. Yeah.
Q. These authors find after 17 years finds that there is no shrinkage of the TVT mesh over time. Is that true?
MR. ANDERSON: Is what true, that it says that on the paper?
MR. THOMAS: That's right.
A. You read it.

Page 179

Q. Okay.
A. It's in the paper there.
Q. Given your testimony on direct examination, is that possible, that of this cohort of 78 percent of 90 women followed for 17 years that there's no shrinkage?
A. If you have a method that is not sensitive enough to detect shrinkage, then of course you will not find any -- any shrinkage. If you are looking at it with inappropriate tools, yeah, it's not missed.
Q. Do you -- do you doubt the findings of the authors in this study that there's no shrinkage after 17 years?
A. I can't comment on it because I don't know the details. I know that we have some rare patients which do not have shrinkage, yes.
(Klinge Exhibit No. 6 was marked for identification.)
Q. Let me show you what I've now marked as Klinge Trial Exhibit No. 6. It's a study by Lo, et al., on an Ultrasound Assessment of Mid-urethra Tape at Three Years.
MR. ANDERSON: Do you have a copy?
MR. THOMAS: I do.
MR. ANDERSON: Thank you.
Q. And that evaluated 80 women who underwent a TVT procedure, correct?

Page 180

A. Eighty women with a TVT.
Q. And they were followed for three years?
A. Yes.
Q. And of the 80 women 85 -- 88.5 percent were objectively cured and six had improved, correct?
A. I cannot follow where you're reading it.
Q. Right under results.
A. Yeah.
Q. Of the 70 women available for evaluation at post-operative year three, 62, which is 88.5 percent were objectively cured and six had improved -- improvement, correct?
A. Yes.
Q. And these authors examined these women by ultrasound at three years, correct?
A. Yes.
Q. And they concluded that, from the ultrasound, that the observations of the tape position and characteristics suggest that shrinkage and compromise to the TVT sling does not occur, correct?
A. You read it correctly.
Q. And this is an objective measurement through ultrasound, correct?
A. Ultrasound hardly -- it is somehow objective

Page 181

but somehow it depends from the specific details of the investigation, from the experience, from the frequency you are applying to the tissues and how you are doing it. So there are a lot of possible modifications of how ultrasound is done.
Q. But at least these authors, using ultrasound, found no shrinkage at three years for the people they examined, correct?
A. In their setting obviously they described no.
(Klinge Exhibit No. 7 was marked for identification.)
Q. Let me show you what I've marked now as Klinge Trial Exhibit No. 7. Klinge Trial Exhibit No. 7 -- excuse me. I don't mean to throw it at you.
MR. ANDERSON: Okay.
Q. Klinge Trial Exhibit No. 7 is a study done by Emily Lukacz, and others, titled, The Effects of the Tension-Free Vaginal Tape on Proximal Urethral Position: A Prospective, Longitudinal Evaluation. And they looked at 94 patients for one year, correct?
A. Yes.
Q. And they used a -- what they call a Q-tip test to determine whether there was shrinkage or tightening of the sling over a year, correct?
A. It's written in the text.

Q. And in this study, of these 94 patients after a year, these authors concluded that there was no shrinkage or tightening of the sling, correct?

A. That's how it's written in the text. I don't have any opinion to this technique or this method.

(Klinge Exhibit No. 8 was marked for identification.)

Q. Okay. Let me show you now what I've marked as Klinge Trial Exhibit No. 8. Klinge Trial Exhibit No. 8 is a study by Dietz, and others, from Australia, Denmark and New Zealand, titled, Does the Tension-Free Vaginal Tape Stay Where You Put It? And this is a study from 2003 in the American Journal of Obstetrics and Gynecology, where they looked at 72 women, out of 92 eligible, at a median interval of 1.6 years to evaluate whether the TVT device implanted in them had contracted or shortened over that time. Do you see that?

A. I see what?

Q. That that's what they were doing. That they looked at 72 women after -- at least twice after TVT placement at a median of 1.6 years to evaluate whether the TVT tape stayed where it was originally implanted.

A. So it's written in the text, yeah.

Q. And this study found, from their review of 72 women, at a median of 1.6 years, that the TVT does not

contract or shorten over that period of time, correct?

A. You read it correctly, but I don't have any comment on the quality of the data and whether it's even enough to see any differences. So the absence of a difference usually is due to the setting of the study, very, very often.

Q. Are you suggesting in the studies that we've talked about that these folks just missed it?

MR. ANDERSON: Objection to form.

A. I cannot comment on it. I don't have it. You have to check it very carefully. You have to check the number of patients. You have to check the technique, how to make it. The problem is that if you don't see any difference you have to be very careful if you missed it just by the setting.

(Klinge Exhibit No. 9 was marked for identification.)

Q. Let me show you what I've marked now as Klinge Exhibit, Trial Exhibit No. 9. Klinge Trial Exhibit No. 9 is a 2015 study in the International Journal of Surgery titled Large Pore Size and Controlled Mesh Elongation Are Relevant Predictors For Mesh Integration Quality and Low Shrinkage. And this is a study by Dirk Weyhe, W-e-y-h-e, William Cobb, and others, about large-pore meshes. Do you see that?

A. I see this document, yeah.

Q. And this is a study conducted in minipigs, 20 female minipigs, correct?

A. That's how it's written in the text.

Q. And in this animal study comparing different pore sizes of mesh, meshes that were devised for this test by Covidien, they found that the larger pore size and lack of stability in lightweight meshes leads to shrinkage. Isn't that what they conclude?

A. The major message of this article is written in the title. Large Pore Size Are Relevant Predictors For Mesh Integration Quality and Low Shrinkage. That's their main message in this article.

However, you are right. They found that if you have a structural instability of the meshes you can have a collapse of these pores, and therefore the stability of a mesh to some forces is a relevant issue as well. But the main message is large pore as I've outlined in the past hours.

Q. But the second bullet point says, "Large pore size and lack of stability in lightweight meshes leads to shrinkage." That was their conclusion, correct?

A. That is what you -- yeah, you read it correctly.

Q. Do you have 8338 in front of you, the Najjari

article? I'll give you another copy of it, just so you have it handy.

On direct examination you were asked questions about Plaintiff's 8338 about the implantation of PVDF as opposed to polypropylene slings. Now that's a follow-up study of some work that you had done with this same group, correct?

A. This is a study by the urogynecologists.

(Klinge Exhibit No. 10 was marked for identification.)

Q. Let me show you what's been marked as Klinge 10. And Klinge 10 is an abstract by Dr. Najjari which compares different types of suburethral slings using ultrasound, correct?

A. Yes.

Q. And you're a co-author on this study, correct?

A. That is correct.

Q. And in Exhibit No. 10 the authors identify differences between PVDF slings and polypropylene slings, correct?

A. Sorry, in which article?

Q. Ten, Exhibit No. 10.

A. This one?

Q. Correct. Exhibit No. 10 preceded 8338, correct?

Page 186

A. I think so.
Q. Yes.
And in Exhibit No. 10 the authors identify what they describe as differences between the placement of the polypropylene slings and the placement of the PVDF slings, correct? It's a study in which you're an author.
A. In both articles you have significant differences between the two groups.
Q. But certainly on Exhibit No. 10 you appear as an author and they've identified these differences, correct?
MR. ANDERSON: Do you have a copy of that?
MR. THOMAS: I thought I gave you a copy. I'm pretty sure I did, because I don't have another one.
A. Yeah, I've been co-author and they identified some significant differences here, yeah.
Q. Okay. But in Exhibit 8338, which is published after Klinge Exhibit 10, they were unable to find any difference between the slings and the improvement of continence, and no significant influence of the parameters was found for the resulting state of continence, correct?
A. You read it correctly. But, in fact, they described the same significant differences as in the

Page 187

other study, they just could not find any relationship to the clinical outcome. And that is reasonable because it is underpowered. With this number of patients you will never get it.
Q. So the bottom line is, in 8338, these authors were unable to tie any of the findings that they made in Exhibit No. 10, where you appeared as an author, to any clinically significant conditions in the patient, correct?
A. In the article for the first time they tried to make this linkage to the clinical outcome. But it is -- it is impossible to do so because it is so -- so much underpowered. And if you are looking to the data you have a huge standard deviation, so there is no way to link this. So the absence of a difference does not mean that there is no one, it is just a limitation of the setting.
Q. And for Exhibit 8338 you're no longer listed as an author, correct?
A. My contribution is very, very limited because I just made some statistical analysis, and so you need some specific contributions to be listed as a co-author in an article. And, therefore, I'm not -- I didn't make any significant contributions to this article and therefore I'm not listed as a co-author there.

Page 188

Q. Thank you.
You are unaware of any clinical studies that show the use of PROLENE mesh increases the risk of injury to a patient in the treatment of stress urinary incontinence over a larger pore, lighter weight mesh; true?
A. I'm aware of some clinical studies trying to compare or to look to the outcome when using large pore lightweight constructions.
MR. ANDERSON: Wait a minute.
A. But I'm very -- I'm aware of the fact that there is no sufficient clinical study comparing two different materials with sufficient statistically power.
Q. I don't think your answer is very clear. I'm going to ask the question again. Forgive me.
MR. ANDERSON: Objection to your characterization.
Q. You're unaware of any clinical studies that show the use of PROLENE mesh increases the risk of injury to a patient in the treatment of stress urinary incontinence over a larger pore, lighter weight mesh; true?
A. We just discussed the findings from Najjari. This is a clinical study. They found significant differences when comparing these two materials. There's

Page 189

maybe some other studies comparing this material showing that large pore, lightweight meshes are superior.
Q. But --
A. But, however, it is not -- I don't know any clinical study with sufficient power which really addresses the comparison of two materials. Either it's lightweight or large pore.
Q. You know that there are multiple manufacturers of polypropylene mesh used for the treatment of stress urinary incontinence in the United States?
A. Sorry. That was a little bit fast for me.
Q. I apologize.
You know that there are multiple manufacturers of polypropylene mesh used for the treatment of stress urinary incontinence in the United States.
A. I don't have any -- any opinion on this. How many manufacturers, I don't know.
Q. Do you know of any device -- strike that.
Do you know of any polypropylene TVT device -- strike that.
Do you know of any polypropylene sling used for the treatment of stress urinary incontinence that has a pore size larger than TVT?
MR. ANDERSON: And I'm going to object to the form.

Page 190

A. A sling with a pore size that is larger, I don't have the data, the exact data.
Q. Okay. You don't know whether any of the meshes, the polypropylene meshes, marketed in the United States for the treatment of stress urinary incontinence have an effective porosity greater than a thousand microns, do you?
A. Though we haven't tested it, I'm sure that, for example, Restorelle, will be much more resistant to the -- to the collapse of pores under tension. So maybe you're right for the textile effective porosity; but the porosity and the mechanical load, there are others where I would suppose that they have a higher effective porosity.
Q. Doctor, let me direct your attention to Page 400 of your deposition on November the 15th, 2013.
Line 14, I asked you the question:
Do you know whether any mesh used for the treatment of stress urinary incontinence available in the United States has an effective porosity of greater than a thousand microns as measured by the Muhl study, Exhibit 20?
Answer: No, I don't know.
Did I read that correctly?
A. You read this correctly.

Page 191

Q. By the way, you know now that Ethicon markets a hernia mesh that you would describe as a small-pore heavyweight mesh, correct? You know that, a five mill hernia mesh. Do you know about the five mill hernia mesh?
A. No, I don't have any information about this.
Q. Okay. So you don't know whether Ethicon today makes a hernia mesh for the repair of hernias that actually has pore sizes smaller than the TVT device.
A. I don't have any information about this.
Q. Okay. Let me show you what I've marked as Klinge Trial Exhibit 17.
MR. ANDERSON: 17?
(Klinge Exhibit No. 11 was marked for identification.)
Q. Klinge Trial Exhibit 11. We talked before, Dr. Klinge, about the forces that a sling would experience after placement for the treatment of stress urinary incontinence. Do you recall that?
A. Yes.
Q. And I believe you told me that you never specifically measured the forces that are applied to the mesh for the treatment of stress urinary incontinence; true?
A. We didn't do our own measurements.

Page 192

Q. Did you consider the study by Drs. Lin, et al., that measured exactly the in vivo tension sustained by fascial sling in pubovaginal sling surgery for female stress urinary incontinence?
MR. ANDERSON: Objection to the form of that question.
Q. Have you ever seen this study before?
A. I'm not sure. I do not remember at the moment.
Q. Down at the conclusions it says, "The fascial sling only sustains minor" -- strike that.
In the conclusions the authors state, "The fascial sling only sustains minor tension, which is far less than the maximal load needed to break the fascial strips."
Up above they have the results found by the tensioning, and you see they're all less than .05 kilograms. Do you see that?
MR. ANDERSON: Where are you referring to, Counsel?
MR. THOMAS: Under results, mean tension, during the cough in the horizontal position was .046, plus or minus .004, etcetera.
Q. Do you see that?
A. Where --
MR. ANDERSON: He's pointing to these figures.

Page 193

A. Yeah, I see that, uh-hum.
Q. And the findings here are that the pressure that's exerted at a maximum under the test that they applied was .05, correct, kilograms?
A. You read it correctly, yeah.
Q. Okay. And what these authors were trying to do were trying to figure out what kind of tension would be placed upon the sling once it had been placed in the woman for the treatment of stress urinary incontinence, correct?
A. So far on the first glance I just can see that they are looking for the forces when filling up the bladder. This is one strain. Other strain is standing up, coughing, pressing, all these other things.
Q. Well, look at the first page, the first paragraph. "The in vivo tension sustained by the sling. We designed this study to obtain this information." That's the purpose of the study, correct?
A. You read this correct, but I -- this is a very complex system to measure forces. It is largely influenced by the way, how you make it, by the -- by the patients, by the conditions around it. So to analyze this you need some time to discuss the data. It is not so -- so simple that you can just put a -- a measurement and then you get some figures.

Page 194

Q. Okay.
A. I would need more time to discuss this in detail with all the limitations of the measurements.
Q. Okay. When you and Professor Muhl designed your test to pull on the mesh to determine the extent to which the pores deformed, the smallest weight that you used was what?
A. One U, a hundred gram.
Q. And that's .1 kilograms, correct?
A. Point one kilo.
Q. Which is twice as much as the maximum force that Dr. Lin found in her study, correct, as being the force that's applied on the sling.
A. In this setting they found lower values, yeah.
Q. Okay. So and the values that you and Dr. Muhl tested began at a 102 grams and went up.
A. Yeah, but it's -- it's far less below the values that are considered by the people from Ethicon or by Moalli and others.
Q. Okay.
A. So I'm not -- I doubt that you can adopt this study to this -- to the definition of the forces that are applied to a -- to a sling in all conditions.
Q. Are you concluding that now without having read the study?

Page 195

A. No, of course not.
Q. Of course not.
MR. ANDERSON: He's just answering your questions, Dave.
Q. And but the point of the matter is, the lowest value that you and Dr. Muhl tested was 102 grams, correct?
A. That is true. But the critical thing is not the lowest value, the critical thing is to be resistant to any deformation that may occur because of higher values.
Q. Okay. Now, you have no idea how this -- when you and Dr. Muhl conducted your testing the results of the tests had you left the mesh -- strike that.
You have no idea what the results of the tests would have been had you left the sheath on the mesh and pulled on either end, correct?
A. As the sheath has a -- is cut in the middle, I cannot imagine whether it will change any of the results. But, just to add it, when we have to analyze just values below one U, that would mean that the PROLENE mesh, the TVT mesh, is much more overengineered that we have been estimating.
MR. ANDERSON: Objection.
Q. Doctor, you have no idea what the results of

Page 196

the tests would have been had you left the sheath on the mesh and pulled on either end, correct?
A. I have no idea, but I don't have any suspicion that it will change the results because the sheath is cut in the middle.
Q. Do you under -- strike that.
And that's because you think that when the mesh is placed that the middle is pulled by the doctor.
MR. ANDERSON: Objection.
A. May I demonstrate?
Q. Sure.
A. If you pull on both sides.
Q. That's how you think it's placed?
MR. ANDERSON: Objection.
A. No; but this happens when you applied some forces.
Q. Okay.
A. Even with the sheath on it.
Q. Okay. But you've never -- hold both ends of the sheath, please. You've never taken --
A. This one?
Q. Yes, like that.
You've never taken the mesh in the sheath as you hold it in your hand and tested what happens to the mesh when you pull on that sheath, correct?

Page 197

A. Yes, it is correct.
Q. Thank you.
A. I didn't test it.
Q. Now, we talked about Dr. Muhl's testing and your reliance on Dr. Muhl's testing. Is the FEG DynaMesh the only mesh, to your knowledge, that passes your effective porosity test?
MR. ANDERSON: Objection to form.
A. I don't have any data to -- to say whether other meshes pass this test.
Q. Let me ask this question: Is DynaMesh the only mesh that you know passes your effective porosity test?
MR. ANDERSON: Objection to form.
A. It is the only mesh that we measured in this publication in comparison to the TVT.
Q. And just so the jury understands, when you tested the PROLENE mesh you tested it at a thousand microns, correct, in all directions?
A. Yes.
Q. When you tested the DynaMesh PVDF you tested it at 600 microns, correct?
A. To explain for the jury --
Q. But answer yes first and then you can explain.
MR. ANDERSON: Don't tell him how to answer.
Q. Okay. Let me start over again. You can

explain all you want to, Doctor.
It's true that when you tested the DynaMesh PVDF mesh you tested it at 600 microns as opposed to a thousand microns; true?
A. That is true.
Q. Okay. Do you know whether if you tested the PROLENE mesh at 975 microns, whether it would pass your effective porosity test?
A. We didn't make the calculation at another diameter of -- the critical diameter for the holes as it is polypropylene. It would just answer the question what happens if you made the TVT out of PVDF and you would get an answer. That we didn't do.
Q. Okay. And so you don't know whether the PROLENE mesh would pass at 975 microns on your test, correct?
A. Yeah, we don't know. I don't know.
Q. You don't know if it would pass if you did it at 990 microns, correct?
A. That is correct.
Q. Just for the benefit of the jury, can you see a micron?
A. With the help of a microscope, yeah.
Q. Can you see 10 microns?
A. With the help of a microscope, yes.

Q. A human hair's, what, about 60, 70, microns thick; is that right?
A. I don't have an opinion about this.
Q. Okay. And just so the jury understands, under the Muhl test, when you're measuring the effective pores, if you don't get a thousand microns in any one of the directions then that pore size is judged to have zero effective porosity, correct?
A. That's the way it calculates. But the aim of the procedure is to predict the risk for fibrotic bridging, and therefore it does not depend on a specific number, whether it's one millimeter or 99 or so. But it reflects the visual impression that you have a collapse of these pores, and it allows you to quantify this effect and to predict the risk for a specific textile.
Q. And at least in January of 2003, it was your opinion the limit for pore size was six to 800 microns, correct?
MR. ANDERSON: What page are you on?
Q. I'm not impeaching him, I'm just asking him a question.
MR. ANDERSON: Okay. If you're asking him about a deposition I think it's fair to let us know what you're looking at.
Q. Is it fair to understand that a true statement

of your research as of January, 2003, the state of your research was the limit for the pore size would appear to be six to 800 microns.
A. Do you have any reference for me so that I can really see the context where we presented it?
Q. Can you remember? I'll be glad to show you the deposition. I'm not trying to trick you.
MR. ANDERSON: Okay.
Q. It's on Page 241 of your deposition on November the 14th of 2013.
A. I know that --
MR. ANDERSON: Hold on. Page 241 you said?
MR. THOMAS: That's right.
Q. Read all the way to 242. I think you need to read the whole thing to get the context.
A. So, please, what was the question for this?
Q. At least in January of 2003, it was your opinion that the limit in pore size was six to 800 microns, correct?
A. Well, you have to see this in the context. As I outlined here in this, it was the process where we had been looking to the critical limits to -- to the holes, whether there is a critical limit.
We just had made large holes of three to four to five millimeters. These are really large pores and

we wanted to know whether the small pores -- whether there is a critical limit, and we made some experiments, and they are influenced by the setting. They are influenced whether it was a thinner polypropylene filament, whether it was used within the abdominal cavity or whether it was used within other tissues. And therefore, in this time period, we got some different values. We presented, as a result of these studies, the best information we had.
But, however, the large pore was the VYPRO and the ULTRAPRO, with three to four millimeter. That is far away from whether it's 600 microns or 800 microns. And you are right. This is a small distance. It is impossible to see the difference. But the large pores, you are able to see the difference.
Q. You don't have a study where you analyzed tissue reactions in animals, or humans, that shows you that pore size over 1,000 microns creates scar plates -- excuse me -- creates scar net and pore size under a thousand microns creates scar plate. You don't have that kind of study, do you?
A. This is not the result of an estimate, this is the result of studies. These are our experimental data we have at that time. We looked to hundreds of stainings and -- and measured the distance between the

fibers and are looking where are some distances where we have some filament. And these are the good distances, and these give the information, the estimate that we said, okay, we need a pore size of at least 800 microns to avoid this bridging by scar. These are experimental data, but we made it in several different tissues.

Q. Doctor, can you point to me any publication upon which you rely to support your position in the testing that you've done with Dr. Muhl that 1,001 microns in all directions is good mesh and 999 microns in all directions is bad mesh?

A. If you want to stick on the number, a thousand microns, recently you showed the publication from Weyhe showing that the large pores is the main point that influences the quality of tissue integration. That's the point.

Q. I understand.

A. Not pores. And the risk for bridging is higher the smaller the pores and it's lower the larger the pores. And it is ridiculous to fix it to 1,000 and believe that 1,001 is completely different and 999 is completely different as well. This would mislead the -- the goal for these measurements. We are not able to make this clearcut and say below one millimeter is good and the other is bad.

Q. Okay. Isn't that exactly what you've done with the opinions that you've given here about saying that Ethicon's PROLENE mesh has zero effective porosity, therefore, it must be a risk to these patients?

A. It objectifies that the pores -- that the holes are small, that the holes even become smaller below this limit of one millimeter when applied some tension to it. And these are facts that increases the risks, in comparison to other meshes that have a hole size that is much bigger. This is confirmed by all our histological studies because we could see that there is scar in the holes and no fat.

Q. If we go back to the Muhl study on P8342, do you have that? I can give you my copy if it helps you.

A. This is the report from Muhl. You mean the report or the publication?

Q. No, I want the report.

First of all, go to Page 8. Page 8 shows -- you went over those images on direct showing the amount of force there. The lowest force you did was 102 grams. You didn't do anything less than 102 grams, correct?

A. That's correct.

Q. Now, it's true that upon the initial tensioning that the TVT device did have effective porosity because the tensioning expanded the pores, correct, on Page 4?

You see Page 4, the last bullet point?

A. Yes, I see it.

Q. And so you don't know what the tensioning would have been at 50 grams as measured by Dr. Lin, do you? You don't know what the effective porosity would have been there.

A. We didn't measure it.

Q. Okay. And you don't know whether it's more than 13.9 percent effective porosity, correct?

A. I didn't get the question.

Q. You don't know whether it's more than 13.9 effective porosity.

A. As I said, we didn't measure it.

Q. Okay. And at least --

A. But to -- to make it clear, effective porosity of 13, 14 percent indicates that 86 percent of the area is covered by scar. That's what the figure is meaning.

Q. That's what it represents, but there's no scientific proof to say that that mesh as configured is going to have 86 percent covered by scar. There's no scientific data to support that because the thousand figure is an approximation that you made not on any scientific data; true?

MR. ANDERSON: Objection.

A. That's not true. A thousand -- these are the

results of the experimental data, and up to now I didn't find any other experimental data, and this is the limit that is acknowledged by Ethicon people as well that is not disputed. There is no one in the world saying that the bridging does not occur or that it is suitable or it's safer to have smaller pores, no.

(Klinge Exhibit No. 12 was marked for identification.)

Q. You have in Klinge 12, which is the New Objective Measurement in your 2007 article when you first reported this new testing technique, one of the meshes you tested was TiMesh, correct?

A. Yes.

Q. And you found that TiMesh had zero percent effective porosity, didn't it, Doctor? Correct?

A. That was found here, yeah.

Q. That's the result of your tests, correct?

A. Yes.

Q. In another publication you analyzed TiMesh and you found that it had good biocompatibility, didn't you, in the 2004 study? Do you remember that?

A. Which study do you mean, in which context, in which model, for which parameter? Good biocompatibility means so many things.

Q. Okay. I need a Julie.

I'll withdraw that question.
MR. ANDERSON: He said I'll withdraw the question.
MR. THOMAS: What number are we?
MR. ANDERSON: I think we're at 13 now.
(Klinge Exhibit No. 13 was marked for identification.)
Q. Now, Doctor, I'll hand you what's been marked as Klinge 13. Klinge 13 is a mesh classification that you and Dr. Klosterhalfen proposed in 2011, correct?
A. That is correct.
Q. And Exhibit No. 13, on Page 253, you identify Class I large-pore meshes, correct?
A. You mean this paragraph here?
Q. I'm on Page 253, in the classification.
A. 253.
Q. There you go. You see where it says large-pore meshes is Class I?
A. Yes.
Q. Characterized by a textile porosity of greater than 60 percent.
Now, you know from your table on Page 255 that PROLENE has a textile porosity of 56 percent, correct?
A. I assume, yeah.
Q. It's on Page 255. It says, PROLENE textile

porosity, 56 percent. Do you see that?
A. Yeah, 56 percent.
Q. And if you had measured 60 percent it would have passed your test, correct, into a Class I large-pore mesh, correct?
A. Maybe this -- this will be one solution to this.
Q. Okay. And then it says that if you have an effective porosity of greater than zero percent you also classify -- qualify as a Class I mesh, correct?
A. In this proposal we -- we wrote this, yes.
Q. Okay. Well, we just decided that when Professor Muhl attaches a hundred grams of tension to the PROLENE mesh it has an effective porosity of greater than zero percent, correct?
A. Please, again.
Q. We just decided that when Professor Muhl attaches a hundred grams of tension to the PROLENE mesh it has an effective porosity of greater than zero percent, correct?
A. Yes.
Q. So under your classification in 2011, PROLENE, if it has an effective porosity of zero, greater than zero percent, qualifies as a Class I mesh, correct?
A. This classification that we proposed is not

applicable for meshes used in the pelvic floor.
Q. Okay.
A. Because they -- yeah.
Q. Thank you.
Is this only for hernia repair?
A. It is for meshes in a tension-free condition.
Q. Okay.
A. It does not consider the application of tensile forces.
Q. All right. So if the mesh is placed in a tension-free condition, these rules apply.
A. This will -- this is in -- in accordance to the data.
Q. You recognize in that study, by the way, that any definition of large or small-pore meshes is arbitrary and influenced by test conditions. Do you agree with that?
A. I totally agree that to find the specific value it is depending from the setting. It does not depend from the setting the -- the major finding that the larger, the safer.
Q. Dr. Klinge, when you conducted your tests with Dr. Muhl in 2007 on the effective porosity and measuring effective porosity, one of the things that you -- one of the meshes that you measured was a TiMesh Light,

correct?
A. Yes.
Q. And you determined in 2007 that TiMesh Light had zero effective porosity, correct?
A. That's what we measured.
(Klinge Exhibit No. 14 was marked for identification.)
Q. Let me show you what I've had marked as Klinge Trial Exhibit 14. Klinge Trial Exhibit 14 is an article prepared by Dr. Junge, and others, including yourself in 2004, analyzing the addition of titanium to a polypropylene mesh for hernia repair, effect on biocompatibility. This is the same mesh that you analyzed in 2004 that is the subject of the measuring that you did in 2007, correct?
A. There are so many modifications of the TiMesh, I have to verify lightweight -- yeah, it seems to be the same, similar.
Q. The same mesh.
And if you go to the last page, when you're analyzing the biocompatibility of adding titanium coating to the polypropylene mesh, you looked at the histology of the animal studies that you did, correct?
A. Yes.
Q. And you conclude, on Page 118, the last

Page 210

paragraph, "To summarize, both mesh modifications investigated showed an overall acceptable biocompatibility, as known from previous studies for low weight, large porous, and monofilamentous mesh structures." Was that your conclusion?

A. The conclusion of this is when you made this weight reduction to 35 grams, when you reduce the thread size to 80 microns instead of 160 of the PROLENE, and if you add some titanium coating to the surface, then you get excellent results. And this obviously is not reflected by the value of the effective porosity. So it may or it is likely that if you use this mesh instead of the PROLENE mesh you have better results, you have less risks.

Q. But you don't know until you test that, correct?

A. You have to test it in many different settings. In particular, you have to look to the tissues. But, again, this is a confirmation that material reduction, thinner threads, may be a coating of the surface, this helps to improve the tissue integration.

Q. So at least for TiMesh, it failed your effective porosity test but passed your biocompatibility test, correct?

A. I cannot say which is a biocompatibility test.

Page 211

It is like I wanted to express, that you have a better tissue reaction when reducing the amount of the material, when you reduce the size of the thread and when you add some coating to make it more heterophobic, then you can improve the tissue reaction, yes. And obviously this is not reflected by the measurement of the effective porosity.

Q. Now, in your career you implanted mesh for hernias about 300 times? Does that sound about right?

A. That's possible.

Q. And when you use mesh for the treatment of hernias you usually have to trim the mesh, correct?

A. That is correct.

Q. And you trim the mesh with scissors, right?

A. Yes.

Q. And when you trim the mesh there are particles that come off of the mesh, correct?

A. We try to trim the mesh out of the -- of the wound on the OR table so that we can avoid that the particles are coming into the wound.

Q. For the millions of hernia surgeries conducted each year using mesh you would expect those hernia surgeries to involve the trimming of the mesh in some way, correct?

A. I don't understand what do you mean by

Page 212

"involve"?

Q. For nearly every hernia surgery that surgeons conduct for the millions every year, there's going to be some trimming of the mesh involved, correct?

A. Some of the meshes will be trimmed by the surgeons, yes.

Q. And in 20 years of mesh research you've never studied the clinical effects of particle loss from mesh, correct?

A. We studied the relevance of surface to the foreign body reaction. We did it. There is no clinical study comparing the amount of particles released during a procedure in relation to the outcome in so far I know.

Q. Doctor, in 20 years of mesh research you've never studied the clinical effects of particle loss from mesh; true?

A. I studied the clinical relevance of an increased surface for a foreign body reaction to the scarring, to the inflammation, yes. But I don't see any way to make a clinical study with sufficient power, with sufficient sensitivity, to come to a result to -- to identify the -- the change in the outcome just by particle in the field of hernia. Because in the field of hernia the particles that are released by trimming is in relation to the surgical trauma and in relation to

Page 213

the mesh area, complete mesh area. It's very, very, a small share.

Q. You've never made a systemic analysis to mesh the extent to which Ethicon mesh is used in the treatment of SUI shed particles in the human body, have you?

A. I don't know what do you mean by systematic analysis.

Q. No quantitative analysis. You've never made a quantitative analysis of the extent to which the Ethicon mesh used in the treatment of stress urinary incontinence sheds particles in vivo.

A. I rely on --

MR. ANDERSON: Objection.

A. -- information from the Ethicon guys about the particle loss.

Q. Can you answer my question, please?

You've not made a quantitative analysis to measure the extent to which the Ethicon mesh used in the treatment of stress urinary incontinence shed particles in vivo. Is that fair?

MR. ANDERSON: Objection; asked and answered.

A. That is true, we didn't make such a study.

Q. Okay. And when you say you relied upon the Ethicon folks about particle loss, you referred to

Plaintiff's 1757. Do you have that in front of you? Can you bring that up, please?

MR. BODYZIAK: What is it?

MR. THOMAS: 1757.

MR. BODYZIAK: Sure.

Q. And if you'll bring up the summary and blow up the summary for the jury.

Doctor, if you'll read along with me, this talks about particle release characteristics of clear and 50 percent blue PROLENE mesh were evaluated. Samples were weighed before and after being subject to -- subjected to 50-percent elongation, paren, most likely well beyond conditions achieved in vivo.

And that's where that data comes from, doesn't it, from an artificial elongation of the mesh up to 50 percent of its length; true?

MR. ANDERSON: Objection to the form of the question.

A. It is coming from this experiment and it assumes the 50-percent elongation that is assumed by other colleagues from Ethicon, yeah.

Q. Okay. This -- the test was to look at 50-percent elongation. You don't -- it's not elongated 50 percent when it's implanted in the human body, is it?

A. I remember there has been documents, internal

Ethicon documents, where it was suggested that you have a maximum 50-percent elongation. So that is -- I don't have any own experiences how often this will happen.

Q. Okay. Do you have any idea whether -- strike that.

A. I even don't know whether it's necessary to make this experiment at an elongation or whether even at a lower elongation of 25 percent you have similar experience. I don't know.

Q. You don't know.

A. I don't know.

Q. The only document you have on which you rely on for the amount of particles that come from Ethicon mesh is Plaintiff's 1757 where they measure particle loss characteristic at 50-percent elongation. Is that true?

A. This is one of the documents.

Q. Do you have any others you can tell me about?

A. I don't remember precisely, but there has been studies before where they compare various materials in regard to the particle loss.

Q. Do you know whether the company ever made a presentation on particle loss between machine cut and laser-cut mesh? Did you ever see that as a part of your work in this case?

MR. ANDERSON: Objection to the form.

A. I don't remember in the moment.

Q. Okay. You'd like to have all the information available to you in order to reach a judgment as to what the particle loss may have been, wouldn't you?

MR. ANDERSON: Objection to the form.

Q. Can you answer the question?

A. Sure, I want to have every -- every type of information that is relevant for making an opinion.

Q. Okay. And you talked about minutes of a 2001 meeting from -- from Dr. Wang, and I don't have the exhibit number because you didn't give it to me. It's a June 21, 2001, memo. Do you know which number that was, Ben, by any chance?

MR. BODYZIAK: 8030.

MR. THOMAS: 8030.

MR. BODYZIAK: P8030.

Q. Would you bring it up, please?

Mr. Anderson showed you the second bullet point, "Fraying is inherent in the product based on mesh construction. When any amount of tension is applied to the mesh, fraying occurs."

A. I remember.

Q. Okay. You've not done your own tests to determine the extent to which the mesh sheds particles at different weights, correct?

A. That is correct, I didn't make these studies.

Q. And looking at Plaintiff's 3045, which is the June 21, 2013, exhibit. Can you bring that up, please?

MR. BODYZIAK: Yes, sir.

Q. This is the Maslow request who sends a photo that says, "Can you suggest any comments on the attached photo?" And the last page shows the photo. Would you show the photo, please?

There's nothing in this letter that gives you any indication about what happened to this mesh before it ended up in this photograph, is there? You don't know how it got there, in that condition.

A. There is no further information than is on the paper.

Q. But the only information about the mesh is the photograph, correct? There's nothing describing what happened to it in the document, is there?

A. I don't have any further information.

Q. Wouldn't you want to know what happened to the mesh before you'd reach any conclusions about what you see in the photograph?

A. The conclusions we had is the unsafe border. It is not only based on this -- on this image, but this image is a confirmation, and it is the confirmation in 2013. So it is not relevant to the safety maybe in 2000

Page 218

and the roping and the curling seen by Moalli and seen by Muhl in his testing. So it's just another confirmation of it.

Q. Okay.

A. If you have another explanation, maybe I will be happy if you can share this information to me.

Q. The only person that knows is Dr. Maslow, correct?

A. What?

Q. Dr. Maslow is the person who knows because he sent the photograph, correct?

A. Yes.

Q. Okay. Now, you've talked about Dr. Moalli several times using the same kind of testing that you did. Dr. Moalli did not remove the sheath -- excuse me -- Dr. Moalli removed the -- strike that.

We've talked today several times about Dr. Moalli and testing they conducted in Pittsburgh on the uniaxial loading of the TVT device. Dr. Moalli removed the sheath before they conducted their testing as well, didn't they?

A. I think so, yes.

Q. You're not aware of any literature showing that fraying of TVT mesh leads to clinically significant results in patients who receive the mesh for the

Page 219

treatment of stress urinary incontinence; true?

A. I don't know of any study focusing on fraying or not fraying or closed borders versus non-closed borders, comparing these two materials, in a clinical trial.

Q. Okay.

A. All our preclinical studies, they confirmed that open borders are a danger and a risk.

MR. THOMAS: Move to strike everything after "clinical trial".

MR. ANDERSON: You asked him are you aware of any literature, any clinical results.

Q. Clinical results.

Doctor, is it true you're not aware of any clinical studies showing that fraying of TVT mesh leads to clinically significant results in patients who receive the mesh for treatment of stress urinary incontinence; true?

A. I don't know of any clinical studies with sufficient power.

Q. Okay. And you know of no study that discusses the risk of particle loss in vivo from Ethicon mesh for the treatment of stress urinary incontinence; true?

A. I'm aware of many literature all confirming that increased surface means a risk for the patient and

Page 220

for the tissue reaction.

Q. But, Doctor, it's fair to say you're aware of no clinical study that specifically discusses the risks associated with particle loss in vivo from Ethicon mesh for the treatment of stress urinary incontinence; true?

A. Clinical studies comparing mesh without particle loss and with particle loss and looking to the outcome, whether there is a difference between them, I don't know any study and I don't believe that it is feasible to make it with a sufficient power, with sufficient patients to find it out, in a clinical setting.

Q. It's true that you don't have any clinical data to link what you understand to be fraying, particle loss, machine-cut mesh, laser-cut mesh, curling and roping, in any clinically significant conditions; true?

A. Clinical in the specific way that you mean clinical study comparing two different materials, that is true. If you accept clinical data as for the general principle that increased surface means increased risk, that is not true.

Q. Okay. Let me go to Page 412 of your deposition on November 15th, 2013.

Question, on Line 1: Is the same thing true for each of these categories that you have in Heading G

Page 221

of Page 43 of Exhibit 11? Do you have any clinical data to link what you understand to be these conditions, being fraying, particle loss, machine-cut mesh, laser-cut mesh, curling and roping to any clinical -- clinically significant condition?

Answer: No, unfortunately I did not find any study dealing with these problems.

Did I read that correctly?

MR. ANDERSON: Objection; asked and answered; improper impeachment.

Q. Did I read that correctly?

A. You read that correctly, but it depends on the definition of clinical study.

Q. Doctor, it's true that there's no optimal pore size for mesh in the pelvic floor, correct?

A. There is no specific volume that can be said if you have this volume this is optimum and you don't have -- all the other problems are gone as well. In this -- in this meaning, in this context, this is true that you cannot give a guarantee, guaranteeing figure.

Q. Because every textile -- strike that.

Because every textile construction is a compromise, correct?

MR. ANDERSON: Objection to the form.

A. Yes. You can -- you can name it as a -- as a

Page 222

compromise, whatever this means.
Q. It has to be a compromise and you have to compare the risks between different constructions or possibilities of constructions when you're designing a mesh, correct?
MR. ANDERSON: Objection to form.
A. Definitely that is correct, you have to identify the risks.
Q. And the kind of studies you need to address the risk include preclinical studies, functional testing and appropriate textile characteristics, correct?
A. These are three types of studies which you need, yeah.
Q. And it's fair to say you can't go through each of the characteristics of a mesh and say this is the precise way, this is the precise pore and this is the precise polymer you need for a mesh for the treatment of stress urinary incontinence; true?
A. You can indicate for each of the features which are the low-risk characteristic, which are the low-risk properties. But you cannot reduce it to one parameter and ignore all the others. That is not suitable.
Q. And you can't do it until you test them and know how well the mesh works in vivo, correct?
A. Yes.

Page 223

MR. ANDERSON: Just a second. We're ready for a break, Dave. Are you about --
MR. THOMAS: I'm just trying to get done. You can go ahead and take a break. It will help me get organized. I'm sorry.
THE VIDEOGRAPHER: We are off the record. The time is 4:05 p.m.
(Recess from 4:05 until 4:16 p.m.)
THE VIDEOGRAPHER: This marks the beginning of Video No. 4. We are back on the record. The time is 4:16 p.m.
BY MR. THOMAS:
Q. Doctor, you have conducted no studies of the PVDF mesh in the human body for hernia repair, correct?
A. We did a lot of studies investigating PVDF that is used for hernia repair in humans, yes.
Q. But you conducted no studies in humans with PVDF mesh for hernia repair, correct?
A. I did not make a clinical study looking to the results after using a PVDF mesh.
MR. ANDERSON: Just to correct the record, you said we did a lot of studies, not a little studies, right? We did a lot of studies.
THE WITNESS: A lot of studies in the previous sentence.

Page 224

THE COURT REPORTER: Thank you.
MR. ANDERSON: Thank you.
Q. And, to your knowledge, there's only one mesh manufacturer in the world that makes mesh made of PVDF for the treatment of stress urinary incontinence, correct?
A. So far I know in the moment. But it is -- well, in fact, I don't know if there is -- meanwhile there is another manufacturer of -- I recently heard that from Eastern Europe there is someone coming up with PVDF meshes as well, but I don't have any other information.
Q. To your knowledge there's only one mesh manufacturer in the world that sells mesh made of PVDF for the treatment of stress urinary incontinence.
A. That is my knowledge.
Q. And that's FEG, who's here in Aachen.
A. Yes.
Q. And you've worked with FEG since 1994, correct?
A. I bought? I worked.
Q. Yes.
A. Since 1993.
Q. Okay. And FEG still uses polypropylene in some of its products; true?
A. Yes.

Page 225

Q. And you have not told them to stop using polypropylene in their products.
A. I am telling since 20 years the -- that PVDF is the best material.
Q. You have not told them to stop using polypropylene; true?
A. I'm not in a position to tell them what to do and what not to do.
Q. Have you told them to stop?
A. As I said to you, I told them, as I told Ethicon, as I told all the participants at the conferences, that PVDF is the better material and isn't higher risk. I didn't advise the FEG to stop selling polypropylene because this is not my responsibility to -- to give this advice to a manufacturer.
MR. ANDERSON: Can I just correct something? Did you say that PVDF is a better material? Did you say it's a higher risk?
THE WITNESS: No.
MR. ANDERSON: Okay.
BY MR. THOMAS:
Q. You helped FEG develop its PVDF mesh, correct?
A. Yes, that is correct.
Q. And FEG has a patent on that mesh, correct?
A. As Ethicon, the FEG as well has a patent on it,

and I am named there as a contributor to this invention.
Q. Okay. DynaMesh PVDF is heavier than polypropylene, isn't it?
A. It is heavier because of the higher density of the PVDF in comparison to polypropylene, and therefore you cannot take the weight as an indicator of the amount of the material. It's just a specific problem of the chemistry.
Q. But it's two times heavier, isn't it?
A. Yes.
Q. And TVT and DynaMesh PVDF have about the same textile porosity, don't they?
A. Textile porosity, I believe it is in a similar range, but it's not relevant.
Q. Okay. And PVDF is more difficult to handle than polypropylene mesh, correct?
A. Difficulty of handling depends on the skills of the man working at the machine.
Q. And PVDF is more expensive than PROLENE polypropylene, correct?
A. That is -- obviously is correct.
Q. And you don't know whether there are any studies on whether PVDF sheds particles, do you?
A. I don't know any particles or I don't know of any specific particles for the particle loss, but I

would assume that every hosiery or textile that is constructed on a knitting machine, when trimming it you will have some open ends and you will have some sort of particle loss. It is unavoidable. But you can reduce it markedly if you have closed borders.
Q. You don't know whether there are any studies on PVF -- strike that.
You don't know whether there are any studies on whether PVDF sheds particles; true?
A. I don't know any specific study looking for particle loss of the PVDF structures.
Q. And you don't know the tearing forces in the two directions of the PVDF; true?
A. The tearing forces in two directions is -- is a very difficult issue, because it is hardly -- it largely depends on the setting of the experimental settings to make the measurement of the forces in two direction.
Q. But you don't have any data on the subsequent tearing force in the two directions; true?
A. I don't know them in the moment, yeah.
Q. Okay. And you don't know the stretching profile at different loads, correct?
A. Stretching profile, if you are looking at the stretchability at certain load, you can take the data from Muhl's testing where he measured the elongation of

the mesh, of the DynaMesh sling, at various mechanical forces. There you will find the data for this.
Q. But today, sitting here, you don't know the stretching profile of this device at various loads; true?
A. I'd have to look to the data. I believe that the elongation at a certain strain is -- is comparatively low. But we'd have to look to the data.
Q. As a matter of fact, you didn't make a specific study to evaluate the use of the DynaMesh sling, did you?
MR. ANDERSON: Objection to form.
A. Again, it depends of your definition, what do you mean by study. Study in patients? No, I didn't do it.
MR. THOMAS: What number are we, 15?
MR. ANDERSON: Yeah.
(Klinge Exhibit No. 15 was marked for identification.)
Q. Dr. Klinge, I want to hand you what's been marked as Klinge 15. Klinge 15 is the long-term -- Comparison of Long-Term Biocompatibility of PVDF and Polypropylene Meshes. Do you have that?
A. I have it.
Q. And you're one of the authors on this study?

A. Yes.
Q. And this is published in 2011, correct?
A. This is correct.
Q. And in this study you're looking at and analyzing the differences between the biocompatibility between polypropylene and PVDF, correct?
A. That is correct.
Q. Go to Page 297, please. 297, the last paragraph on the right side, says "Although there are many experimental studies dealing with the analysis of tissue reaction for polypropylene and PVDF meshes, so far there are no long-term results of PVDF meshes available and that's important to understand how the mesh performs over time"; is that correct?
A. It is correct that there are no long-term results on PVDF meshes if you're thinking of outcome studies for five years, 10 years.
Q. "Our study shows an excellent biocompatibility of PVDF not only in the short run. To conclude, PVDF shows low inflammation parameters and mature scar preparation" -- excuse me.
"To conclude, PVDF shows low inflammation parameters and mature scar formation after six months. The present data clearly show that PVDF is a possible alternative to polypropylene, despite an increased

effective surface area of the PVDF samples."

So in 2011 you're recognizing PVDF as a possible alternative to polypropylene, correct?

A. That is correct.

Q. And then you're going down and you say, "Rodent model have their natural limitations and results cannot be translated directly to the human situation. In particular, the animals cannot reflect any underlying human disease or comorbidity. Therefore, clinical studies have to be performed to confirm the long-term biocompatibility of the PVDF meshes." That's what you wrote.

A. You read it correctly.

Q. And the purpose of that is so that any manufacturer or doctor has a track record of actual use of the mesh in humans before they make a judgment either to manufacture or prescribe that for their patients; true?

A. I don't understand the question.

Q. The purpose of long-term data is to make sure that it's safe and effective in the patient, correct?

A. Yes.

Q. And you recognize, in 2011, that you do not have any long-term data in order to evaluate whether PVDF meshes are safe and effective in humans, correct?

A. Yeah.

Q. Now, Doctor, in recommending PVDF you're recommending a mesh that is not lightweight, correct?

A. It is not lightweight.

Q. And it's not large pore either, is it?

A. It is large pore.

Q. It's not -- is it one millimeter in all directions?

A. It is not necessary for PVDF to have this amount. When we placed it into tissues and looked we saw fat tissue in the pores. This is the critical point to this.

So the foreign body reaction to PVDF is attenuated in comparison to polypropylene. Therefore, you are able to have more options in the textile constructions. However, a polypropylene mesh like TiMesh may have almost similar results.

Q. But, Doctor, just to be fair, it's not 1,000 millimeters in all directions, correct?

A. Maybe it is not a thousand microns in all directions, but we didn't measure it.

Q. You don't know how large the pore size is, do you?

A. As we measured it.

(Klinge Exhibit No. 16 was marked for identification.)

Q. Let me show you what I've had marked as Klinge Trial Exhibit 16. Klinge Trial Exhibit No. 16 is a study published in Hernia, in 2013, that says DynaMesh in the Repair of Laparoscopic Ventral Hernia, a Prospective Trial, where they look over a five-year period, 181 patients who went -- underwent ventral hernia repair using DynaMesh, and that's a PVDF mesh, correct?

A. Yes.

Q. And folks conducting this study conducted telephone interviews estimating post-operative pain and patient satisfaction, correct?

A. Yes, you read it correctly.

Q. And if you go to the second page you see in box one the results that they got on follow-up in the telephone questionnaire. Do you see that?

A. Yes.

Q. And of the -- of the patients who responded, 16 percent reported mild pain, correct?

A. So it is written in the table.

Q. And 16 percent reported moderate pain, correct?

A. That is correct.

Q. And three percent reported severe pain, correct?

A. So it's written in the box.

Q. So 19 percent of the people reported severe or moderate pain after receiving a PVDF mesh for the treatment of their hernia, correct?

A. That's how it's written in the study.

Q. And if you include the mild pain it's 35 percent of the people who received the PVDF mesh for their hernia repair had some kind of pain that they reported, correct?

A. So it's written in this study. But you have to consider that it is a completely different setting. So when using a mesh in a laparoscopic incisional hernia repair, you are forced to make a lot of fixations, and a lot of fixation means a lot of pain to the patient. So there are a lot of confounders that are influencing the result as well.

Q. And this follow-up, the median follow-up is 34 months, with a range of 12 to 63 months, correct? First page down at the bottom left.

A. Yeah.

Q. Okay. And that's the time frame in which those reports of pain are reported, correct?

A. Yes.

Q. Going back to Deposition Trial Exhibit No. 1, this is the Safety Considerations For Synthetic Sling

Page 234

Surgery. This is the report by Dr. Blaivas, and others, plaintiffs in this litigation, who reported on the complications of retropubic slings, correct? Remember that?

A. I remember.

Q. And these experts collected a series of studies and report only 1.8 percent of long-term pain, correct?

A. That is correct.

MR. THOMAS: Let's go off the record for a second, please.

THE VIDEOGRAPHER: We are off the record. The time is 4:36 p.m.

(Recess from 4:36 until 4:37 p.m.)

THE VIDEOGRAPHER: We are back on the record. The time is 4:37 p.m.

BY MR. THOMAS:

Q. Now, Doctor, you've been a paid consultant for FEG since about 1988 or 1989?

A. No, I'm a paid consultant just from 2006, I believe, 2005 maybe.

Q. So for the last 10 years you've been a paid consultant for FEG?

A. Yeah, after -- after the consulting activities with Ethicon stopped.

Q. Okay. And just so the record's clear, you

Page 235

receive royalties from Ethicon for VYPRO I, VYPRO II and ULTRAPRO, correct?

A. That is correct.

Q. And to this day you're compensated annually by FEG, correct?

A. That is correct.

Q. And I believe you told Mr. Anderson that they pay you about 40,000 euros a year?

A. Totally, yes.

Q. Okay. And how many years have they paid you 40,000 euros a year?

A. I -- I don't remember.

Q. The last five years?

A. No, no, no, no. So even -- even the year before it was less. So I cannot remember.

Q. You told me when we last met that it was $35,000 for each of the last three years. Does that sound about right?

MR. ANDERSON: Objection.

Q. Excuse me. You told me last time we met it was about 35,000 euros each of the last three years. Does that sound about right?

A. Yeah, maybe -- maybe this is true for the last three years, but before it was significantly less.

Q. And FEG determines how much it pays you each

Page 236

year, correct?

A. Yes.

Q. You don't have a contract with them.

A. I don't have a formal contract, yeah.

Q. And the amount FEG pays you depends on how well the company does that year; true?

A. That's true.

Q. And you've spoken at conferences sponsored solely by FEG, correct?

A. As I indicated this morning, in some occasions I talked on conferences that are on behalf of the FEG.

Q. And the distributor of PVDF often reimburses your expenses to attend events, correct?

A. No, they don't often make it. I was -- there has been two or three occasions where I was invited by the distributor, and not by the FEG, where they took over the expenses for the traveling. And overall, in the last 10 years, two times or three times I got some sort of royalty, but most of the time this is not the case.

Q. When did FEG first sell its PVDF mesh?

A. I don't know exactly. I would estimate 2005 maybe.

Q. And about the same time that you retired from surgery?

Page 237

A. No, I -- I stopped active surgery in December, 2006.

Q. Okay. And since 2006 you are teaching, speaking and conducting research; is that correct?

A. That is widely correct.

Q. And I believe you testified on direct that the time that you spend working for the FEG occupies about five percent of your time?

A. Two or three hours a week, but it varies, depending on the -- on the demands on the projects.

Q. And you're paid by the plaintiffs in this case, correct?

A. Yes.

Q. And you're paid at the rate of $500 per hour?

A. That's correct.

Q. Now, have you submitted a bill to the plaintiffs yet for your work in this case?

A. No, not yet.

Q. Okay. Last time we talked about this you had met with Mr. Anderson for about 15 hours to prepare for your deposition, then you had your deposition, correct?

A. Yes.

Q. And you'd also charged I think $10,000 to prepare a report; is that correct?

MR. ANDERSON: Objection; misstates facts.

Q. Strike that.
Well, how much money did you charge to prepare your report in this case?
A. I didn't put up any -- any bills up to now, but I would estimate that overall 60 hours for the entire case.
Q. Okay.
A. Will be -- will be the sum of it.
Q. Does that include your preparation for this testimony?
A. Everything.
Q. Okay. So about $30,000?
A. Yes.
Q. Is that time all spent in calendar year 2015?
MR. ANDERSON: Objection. That's on this case. You're not allowed to ask outside of that and you know it.
MR. THOMAS: That's what I meant.
MR. ANDERSON: Well --
Q. Strike that.
Is the 60 hours that you have identified on this case incurred in calendar year 2015?
A. Yes, I guess so.
Q. Doctor, go back to this document. It's the second one under this stack. I don't know what number

it is. 15? Strike that. I'll withdraw that.
MR. THOMAS: That's all the questions I have, Doctor.
THE VIDEOGRAPHER: We are off the record at 4:43 p.m.
(Recess from 4:43 until 4:45 p.m.)
THE VIDEOGRAPHER: We are back on the record. The time is 4:45 p.m.
REDIRECT EXAMINATION
BY MR. ANDERSON:
Q. Hello again, Dr. Klinge. On cross-examination Mr. Thomas said, you've not designed a PVDF for SUI, have you? And you said, well, I'm not a manufacturer.
Let me ask you this question: Has a manufacturer designed a PVDF for incontinence repair?
A. I don't know any -- any specific design that is created for incontinence repair by any manufacturer.
Q. Does FEG have an SUI sling for incontinence repair?
MR. THOMAS: Objection; asked and answered.
A. In fact this was designed just for this specific purpose. So therefore I have to correct my previous answer.
Q. Okay. Let me ask you again. Is there a manufacturer that makes an SUI sling with PVDF?

MR. THOMAS: Objection; asked and answered.
A. Yes.
Q. And what manufacturer is that?
A. It's the FEG.
Q. And is that the sling that's contained within the 2015 report that you did with Professor Muhl in which you compared the TVT to the PVDF sling manufactured by DynaMesh -- by FEG?
A. Yes.
Q. Mr. Thomas said, asked you some questions. He said, are you aware that a manufacturer has to have FDA clearance before they put a pelvic floor mesh on the market? You remember he asked you that?
A. I remember.
Q. Are you aware that Ethicon put its pelvic floor mesh, Prolift, on the market without seeking FDA clearance?
MR. THOMAS: Objection.
Q. Are you aware of that?
MR. THOMAS: Objection.
A. I read it in the documents from Ethicon.
Q. Are you aware that Ethicon sold their pelvic floor mesh, Prolift, for three years without obtaining FDA clearance. Are you aware of that?
MR. THOMAS: Objection.

A. I am aware of it, yes.
Q. He said, on cross-examination, you've never made any direct measurements of forces applied to mesh for SUI. And your response was, no, I relied on Ethicon. Do you remember that part of your testimony?
A. I remember.
Q. Okay. And you said I believe there were some people within Ethicon who looked at the forces that would be applied. Do you remember that part of your testimony?
A. Yes.
(Plaintiff's Exhibit No. 0636 was marked for identification.)
Q. Showing you what we will mark as P0636. Can you put that up? Let's go down to 2A. Well, first, at the top, E-mail from Gene Kammerer to various individuals within Ethicon. Do you recognize Gene Kammerer as one of the Ethicon scientists?
A. Yes.
Q. Have you seen his name and read his deposition?
A. I've seen it, yeah.
Q. Have you seen lots of documents by Gene Kammerer?
A. Lots of documents.
Q. Okay. And the subject is, Ultrasonic Slitting

Page 242

of PROLENE mesh for TVT. And if you look under 2A, if you could blow that up, please. Is this a document that you reviewed and relied upon in coming to your opinions in this case?

A. Yes.

Q. Okay, 2A. According to Gene Kammerer, "The link between the elongation percent, not force, and the integration of the mesh is this: During the operative procedure as the surgeon removes the protective sheath from the mesh, the mesh stretches or elongates. It is my experience, after viewing many surgical procedures and performing numerous procedures on cadavers myself, that the mesh stretches approximately 50 percent of the maximum." Did I read that correctly?

A. Yes.

Q. Is this part of the information that you relied upon in determining how much force to be placed on the TVT sling when you did your study in 2015?

A. Yes.

Q. And did you in fact place forces that were less than 50 percent in your -- in your testing?

A. We are starting with forces that are -- that are less than the force that is necessary to make this 50 percent elongation.

Q. And let me -- if you could pull up the MCM LCM

Page 243

picture from his report. In your report did you have a diagram of this stretching test that was done by Gene Kammerer at 50 percent?

A. Yes.

Q. Okay. If you could blow that up, please. This is in Klinge's expert -- Dr. Klinge's expert report. Did you review and rely upon this article in forming your opinions?

A. Yes.

Q. Okay. And Mr. Thomas asked you on cross-examination, the only thing that you relied upon in coming to the conclusion that there was particle loss and how much particle loss there would be was that 12 percent study. Do you remember he asked you that?

A. Yes.

Q. Is this also one of the internal Ethicon documents that you relied upon?

A. It's another internal document where they compared mechanical-cut and laser-cut meshes.

Q. And according to this, as well as the E-mail here, which one of these materials shed more particles and had more degradation, the mechanical cut or the laser cut?

MR. THOMAS: Object to the form.

A. The mechanical cut shows more particle loss and

Page 244

shows more roping at the bottom than the laser cut.

(Plaintiff's Exhibit No. 1133 was marked for identification.)

Q. I also want to show you PLT1133. With regard to Mr. Thomas saying this is the only study, this 12 percent that you're relying upon to look at the amount of particles that are shed on a TVT sling when forces are applied to it, if you'll blow that up, the top of that, please. Are you familiar with this Pariente study and is this something you reviewed and relied upon in your opinions in this case?

A. Yes.

Q. Okay. And if you could turn it over and look at the second page, is the TVT sling one of the slings that he did and compared it to other slings and other mesh material when it came to the amount of particles that would be lost under various forces?

A. Yes.

Q. Okay. And if you look over at the final page, Page 12 of this document, if you would just blow up from particle shedding all the way down under Uratape, just that whole left side.

A. Yes.

Q. Which one of the slings that Dr. Pariente studied in this published article from 2006, how much --

Page 245

which one of these had the most loss of particles under force?

A. TVT has a particle loss of 8.5 percent. That is significantly more than all the others.

Q. So, Doctor, whether it's the 50 percent elongation images that we saw with the particle shed from the mechanical cut mesh by Gene Kammerer, or it's the documents that you saw from Dr. Wang, as well as the ones from Dr. Maslow in Canada, or it is from the 12 percent particle loss internal test by Ethicon or the 8.5 percent particle loss test by Dr. Pariente, do you have an opinion as to whether or not this particle shedding and this amount of particles coming off of the product will be unsafe in patients? Do you have that opinion?

MR. THOMAS: Object to the form of the question.

A. Yes.

Q. And have you taken all of these things together in forming this opinion?

A. This particle loss means an increased surface and therefore an increased risk for the patient to have more inflammation and more scarring.

Q. And you were asked a lot of questions about did you do a clinical study on this, did you do a clinical

Page 246

study on this. Do you need a clinical study, Doctor, after your 20 years of experience and all that you've done in the field of biomaterial science to tell you whether or not a curled, roped, frayed TVT mesh with particles off the side is going to create a greater risk to patients than one that doesn't shed particles and curl and rope? Do you need a clinical study to tell you that?

MR. THOMAS: Object to the form of the question.

A. No, I don't think that you will find any ethic committee that allows you to do -- to make such a study.

Q. You were asked some questions about whether or not you removed the sheath before you tested it, and you had some responses about how the sheath is cut in the middle so you don't believe it would change your -- your data. Do you remember those questions?

A. Yes.

Q. Okay. And Mr. Thomas said, well, neither you and Professor Muhl in your tests took the sheath off and Dr. Moalli and her group out of University of Pittsburgh, they did it without taking the sheath off. Do you remember that?

A. Yes.

Q. Have you seen the TVT implantation video in

Page 247

this case?

A. Yes.

Q. And when they're tugging and pulling on the TVT after it's been implanted, does that still have the sheath on it?

MR. THOMAS: Objection to form.

A. No, the sheath has been removed before.

Q. And when they did that 50 percent elongation test with the laser-cut mesh and the mechanical-cut mesh by Dr. Gene Kammerer, did they have the sheath on it?

A. It was always done without any sheath.

(Plaintiff's Exhibit No. 2924 was marked for identification.)

Q. And let me show you Plaintiff's Exhibit 2924 if I could, please, flagging irrelevant page. Is this a document that you reviewed and relied upon in coming to your opinions in this case?

A. Yes.

Q. I'm showing you what we've marked as Plaintiff's 2924. If we turn over to this slide, slide No. 36, and is this -- what is this document? Is this a -- that I'm showing you here?

MR. THOMAS: Objection; foundation.

A. It's an internal Ethicon document where they have been looking for a safer or better design of the

Page 248

sling.

Q. And what -- what mesh material was Ethicon looking at when they were looking at a different design for their sling?

MR. THOMAS: Object to the form of the question.

A. In the large- pore lightweight meshes, the ULTRAPRO.

Q. Okay. And if you blow up that, when they -- when they looked at the mesh tensile testing characteristic of the top images, when they did mesh tensile testing characteristics and looked at this in their own internal studies, did they test it with the sheath on it?

A. No.

Q. Did they do uniaxial testing like you and Professor Muhl did?

A. It is identical to the testing we did and Moalli did, so everyone will do it in this way.

Q. On cross-examination Mr. Thomas said -- he pointed you back to some of your testimony as to whether or not you would use or advocate using VYPRO or ULTRAPRO for pelvic floor repair. Do you remember those questions?

A. Yes.

Page 249

Q. Since that time of your deposition, have you seen any randomized control trials where others looked to see whether or not ULTRAPRO would work as a stress urinary incontinence device?

A. Yes.

(Plaintiff's Exhibit No. 1085 was marked for identification.)

Q. Showing you what's been marked as Plaintiff's Exhibit PLT1085. I think he's going to put it up for you. Blow up the top. Is this a study that you reviewed and relied upon in this case?

A. Yes, I've seen it.

Q. Is this a study that came out after the deposition that Mr. Thomas was referring you to?

A. Yes.

Q. Okay. And what did the Okulu study do?

A. They used the ULTRAPRO mesh for the treatment of urinary incontinence and placed it underneath the urethra.

Q. And after three years of using this in a randomized control trial, what were the results? Were they favorable for using ULTRAPRO or unfavorable?

A. They concluded that it's favorable results for the use of this material reduced large-pore mesh.

Q. Mr. Thomas also made this statement to you.

Page 250

Isn't it true, Doctor, that millions of repairs of polypropylene have been used for hernia repair. Do you remember that?

A. Yes.

Q. Is it also true that there have been thousands and thousands of patient complications and patient injuries as a result of the use of heavyweight small-hole PROLENE mesh for hernia repair? Is that true?

A. That is true.

MR. THOMAS: Object; move to strike.

MR. ANDERSON: If you're going to ask him how many people have done well, let's ask him how many people haven't.

Q. He also said to you, polypropylene is still appropriate to use -- he said still appropriate to use in the pelvic floor in the appropriate design. Do you remember that question?

A. Yes.

Q. Are you aware of whether or not Prolift -- Ethicon's Prolift, Ethicon's Prolift Plus M, Ethicon's Prosima and Ethicon's TVT SECUR are still on the market or off the market today?

MR. THOMAS: Objection; move to strike.

A. They are off the market today.

Q. So evidently they are not in an appropriate

Page 251

design of polypropylene to still be sold on the market today at least according to Ethicon, huh, Doctor?

MR. THOMAS: Objection.

A. That's true.

Q. He also showed you Page 535 of your deposition from November 15, 2013, and he read you some questions and answers but he stopped a little short, so I want to make sure that the jury gets to hear your full testimony. He said --

MR. ANDERSON: That's yours under there, Dave.

MR. THOMAS: Oh, I'm sorry.

Q. We are at the place that you referred him to, which was November 15, 2013, Page 535.

MR. THOMAS: This is not mine.

MR. ANDERSON: Okay. You find that one and I'll swap with you.

Q. He read from you Lines 9 through 22, whether you had an opinion, to a reasonable degree of scientific and medical certainty, as to whether the use of polypropylene in hernia repair done are reasonably dangerous. And he read to the part all the way down to where you said, "But, if I may, it depends on the structure." What he didn't read is the next lines.

Question: Right?

And you said, answer, so it's not a general

Page 252

free comment on polypropylene in general.

So you said it depends on the structure and it's not a general comment on polypropylene in general.

What did you mean by that answer? And I'll give you the context. 535 at the bottom. He started here. He stopped at Line 19. Tell the jury from 20 to 24 and at the top of the next page, when you qualified your answer, what did you mean?

A. A statement that polypropylene is suitable or not suitable, it doesn't make any -- any sense. You can -- it depends mainly from the way, how it is produced. There are -- you can buy knives made of polypropylene. This of course is an inadequate structure. So you cannot answer this question whether polypropylene per se in any structure is suitable or not. It has to be in context with the textile structure.

Q. Mr. Thomas showed you lots of society papers. He even showed you some things on the FDA. He showed you a number of purported clinical data regarding SUI slings. Do you remember those questions?

A. Yes.

Q. So just to clean up this question in case FDA doesn't come in.

Do you remember on your cross-examination that Mr. Thomas asked you a number of questions and showed

Page 253

you a number of documents on society papers or clinical studies on the effectiveness of SUI slings. Do you remember that?

A. Yes.

Q. In any of those papers that he showed you did they address whether or not a heavyweight small-hole polypropylene mesh that has laser cut -- I'm sorry -- that has mechanical-cut edges, that curls, ropes and frays and lose particle, whether or not those are safe and effective?

MR. THOMAS: Object to the form.

Q. Did you see that in any of those documents?

MR. THOMAS: Object to the form of the question.

A. No, I didn't see it in any. There was no comment about -- about this.

Q. Have you ever seen in any of Ethicon's sponsored studies or any of these studies where they make a differentiation between the TVT sling that's mechanical cut versus the TVT laser cut when it comes to safety or efficacy?

A. I didn't have -- I didn't saw any -- any study like this or any document.

Q. In response to -- strike that. New question.

Mr. Thomas asked you on cross-examination if

Page 254

the explanted heavyweight mesh that Dr. Heniford took out of the patient that was on the DVD and that he banged on the table, he said, was that a Bard mesh. Do you remember those questions?

A. Yes.

Q. And you said, yes, but it's the same construction as PROLENE. Do you remember that?

A. Yes.

Q. What do you mean by that?

A. Both that the Bard mesh as well as the PROLENE, they are considered as heavyweight small-pore meshes. And many, many studies clearly show that the tissue response is almost identically between these two.

So it is exchangeable whether you are taking PROLENE or whether you are taking this Bard mesh to create the tissue response that is typical for heavyweight small-pore meshes.

Q. In the Klinge 13 defense exhibit that he showed you on cross-examination, which was the modified classification of surgical meshes, do you remember that document?

A. Yes.

Q. If you look at Table 1 again, which one is the heavier weight mesh, the Marlex or the PROLENE that's used in the TVT?

Page 255

A. The PROLENE is heavier.

Q. What's the weight of the Marlex?

A. It's 95 gram per square meter, whereas PROLENE has 109 gram per square meter.

Q. And when you were just telling the jury -- and when you were just telling the jury that these meshes behave similarly, is part of the reason that these are this class of heavyweight meshes?

MR. THOMAS: Object to the form of the question.

A. Because of the similar reaction of the tissues to these materials, they can put into the same group of the heavyweight small-pore meshes.

(Plaintiff's Exhibit No. 8064 was marked for identification.)

Q. Let me show you Plaintiff's Exhibit 8064. Can you pull that up? With regard to this discussion over Dr. Heniford's video, just taking you back to your testimony, you said that this was played at many conferences. Can you explain what you meant by this video was played at many conferences?

A. I attended or was a participant at many hernia conferences on the European level or on the world level, and there either Todd Heniford showed himself this video or some of my colleagues who probably had access to this

Page 256

video demonstrated or showed this video because it's so impressive and it's typically for the tissue reaction to this material.

Q. And at the end of that video did you notice when it said, funded by, which mesh manufacturer funded that video?

A. I'm not sure that this was shown during the part -- during many of these conferences very often that it's just an extraction. But I know that it's funded by Ethicon.

Q. Okay. So if you'll blow up that first paragraph. It says, "The following is an excerpt from an E-mail from Todd Heniford," that's the doctor who was in this video sponsored by Ethicon banging the hard mesh on the table, right?

A. Yes.

Q. Okay. So, "The following is an excerpt from an E-mail from Todd Heniford as an argument that we need to reduce the mass and inflammatory response in current mesh. It is consistent with the 'potato chip' folding phenomena that has been reported with Kugel. We need to keep in mind that PROLENE may behave in a fashion similar to Marlex." Did I read that correctly?

A. Yes.

Q. Have you reviewed and relied upon this document

Page 257

in coming to your opinions?

MR. THOMAS: Objection.

A. Yes.

Q. And do you review and rely upon this document in coming to your opinion that the PROLENE heavyweight mesh will react in a similar fashion as the Marlex heavyweight mesh?

MR. THOMAS: Objection.

A. In this statement they acknowledge that they know it. But we know from many, many experiments that there is no difference in the -- in the response to these materials.

(Plaintiff's Exhibit No. 8351 was marked for identification.)

Q. Showing you Plaintiff's Exhibit 8351. If you could blow up the top of this E-mail. Is this also a document that you have reviewed and relied upon in this case?

A. Yes.

Q. Okay. This E-mail from Petra Koehler. You know Petra Koehler, right?

A. Yes, very well.

Q. Okay. And who is she?

A. She has been responsible or she has been working in Ethicon, Germany, and was responsible for the

Page 258

clinical studies.
Q. And of course you already told the jury you know who Dieter Engel is, right?
A. Yes.
Q. And you worked with him as well as this guy Boris Batke who's also on this E-mail, correct?
A. Yes.
Q. And under the subject, ULTRAPRO Mesh Registry, if we look down to the -- pick up with the top of that video where it says Von, Heniford, and take it down through the first paragraph. Is this an E-mail from Todd Heniford in November of 2004 back to these individuals in Ethicon?
A. Yes.
Q. Okay. And it says, "Jill, I wanted to give you a bit of follow-up from the ULTRAPRO project that you initiated with our group some time ago."
And then if we look down, "You had a number of talented development people working on ULTRAPRO, a/k/a Edelweiss," that's the project name for ULTRAPRO, correct?
A. Yes.
Q. "Ethicon put a great deal of money behind it, and your new platform was somewhat riding on its success."

Page 259

And if you look down further, "I think the data is clear, the mesh is plenty strong. In fact, I believe that you are on the brink of changing how hernias are performed in North America."
And then if you look at the next sentence, "There is no use for a heavyweight mesh like Marlex at any time or anywhere in the human body and, yes, you may quote me." Did I read that correctly?
A. Yes.
MR. THOMAS: Objection to all this line of questioning about Heniford's comments.
MR. ANDERSON: Please do. You're the one that raised it on cross.
Q. And under here it says -- when it says there's no use for a heavyweight mesh like Marlex any time in the body, do you agree that a small-pore heavyweight mesh has no use in the human body when it comes to a sling repair?
MR. THOMAS: Object to the form of the question.
A. I don't see any reasonable indication in this area of the body.
Q. Oh. Right at the end of your testimony Mr. Thomas showed you a DynaMesh article, Klinge 16, of the repair of laparoscopic ventral hernia. You're

Page 260

familiar with the laparoscopic ventral hernia repair?
A. Yes.
Q. Is it often associated with pain?
A. Very often, yeah.
Q. Explain that why to the jury, please.
A. It's so when you make a laparoscopic hernia you -- you place a huge piece of mesh to the abdominal wall and it is within the abdominal cavity and you are forced to -- to make it a prominent fixation of the mesh. And this is done usually by the use of tacks, spiral tacks, very sharp and two centimeters in size spiral metal clamps that are placed every one, two centimeters circulating around it, and this causes a lot of pain. We all know this.
So the pain is a thing that is related first of all to the -- to the -- to the need for a fixation of the mesh material there. Otherwise you have some -- you have to make a lot of dissection within the abdominal cavity. You have to use specific mesh materials that is integrated there and which may reduce the mobility. So it's a completely -- it's a challenging surgery there.
Q. And whether you use PVDF or polypropylene for a laparoscopic ventral hernia repair, do you expect to see amounts of a third of the patients reporting pain after that procedure?

Page 261

A. This is a usually number. In contrast we know that there are other material that are not so elastic, stretchable than the -- the DynaMesh, they cause much more pain for a much longer time.
Q. Then what Mr. Thomas did on cross-examination was he took the 30 percent pain from a laparoscopic ventral hernia repair trial and he used Klinge Exhibit 1, which was a systematic review by these authors regarding sling studies where he says they reported 1.8 percent pain, and he showed that to you right after he showed you the laparoscopic ventral hernia repair, correct?
A. Yes.
Q. And then he said, well, there's 30 percent or more pain with the laparoscopic ventral hernia repair and only 1.8 percent reported in this metaanalysis of all of these studies in Klinge Exhibit 1. Do you remember that?
A. Yes.
Q. Is it good science to take the results from a six-month laparoscopic ventral hernia repair and the pain those patients report and try to compare that to sling studies that were done with various numbers of patients over various times with various different materials and say that you can relate the less pain in

Page 262

the sling studies to more pain in the laparoscopic ventral hernia repair studies? Is that good science?
A. It is not -- scientifically it is not justified to compare these studies and to compare the figures. It's completely different.
Q. It's not even intellectually honest, is it?
MR. THOMAS: Objection.
A. I don't have any opinion to this.
Q. When he showed you Klinge Exhibit 3, again, he showed you an article on laparoscopic versus open ventral hernia repair. If you could -- and he went into this multivariate analysis on quality of life.
In this 12-month laparoscopic open ventral hernia repair study, did they use PROLENE heavyweight small-pore mechanical-cut mesh to say whether or not it would work better after 12 months versus these other meshes?
A. No.
Q. Is there anything you can draw from Klinge 3, this open ventral hernia repair, compared to whatever the other laparoscopic ventral hernia repair, to determine whether or not the PROLENE mesh in TVT is going to be safe in women?
A. No, it doesn't help.
Q. Any value at all?

Page 263

A. No.
Q. When he talked about Klinge 4 to you, that was the Cobb study where they were looking at incisional hernia and predictors of wound events and recurrence. Do you remember the questions on that?
A. Yes.
Q. And he said to you, emphatically, Dr. Cobb doesn't use lightweight or I guess in this case ultra lightweight meshes, does he?
A. Yes.
Q. And you gave some answers to the jury about the fact that he went to middleweight.
A. Yes.
Q. Okay. I'm just taking you back to that part of your question, back to part of his question.
Explain to the jury what you meant when you were saying that he went from lightweight to middleweight.
A. So there are -- mainly there are three groups of meshes. The one is the heavyweight meshes prototypes are typical of representing meshes of the Marlex and the PROLENE mesh. There are the lightweight meshes, of course. This is VYPRO and ULTRAPRO. And there are -- in between there are some materials that are reduced in weight, such as PROLENE soft or GYNEMESH, and these are

Page 264

called for many people mid-weight, because they are already material reduced, but they have a little bit more material than the lightweight meshes.
Q. Did you see anywhere in that study or of all your review of the scientific literature and your work in the hernia world and speaking at conference anywhere where Cobb, Heniford or any of your colleagues have gone back to heavyweight small-pore meshes as a first line repair for any of their patients?
A. So far I remember they always go in some patients back to the -- to the mid-weight meshes but never to the small-pore heavyweight meshes.
Q. Mr. Thomas went over Klinge Exhibit 5 with you, which was this Nilsson article on 17 years of follow-up of tension-free vaginal tape. Do you remember that?
A. Yes.
Q. And he talked to you about these 70 -- 78 percent of the potential assessable women. Do you remember that?
A. Yes.
Q. So that means 22 percent of the original women were not available, correct?
A. That's true.
Q. So are you familiar with the term, lost to follow-up?

Page 265

A. Yes.
Q. Is a study that has 22 percent loss to follow-up significant to your opinions as to the reliability of the results of the study?
MR. THOMAS: Object to the form of the question.
A. If you are looking to the data that results there, no. It is a -- it has an insufficient power to detect or to be used as a safety study.
And even in particularly if you lost 20 percent of the patients, there is no -- no value in regard to the safety or long-term outcome, safeness of the material.
Q. I heard you mention a few times in your responses to Mr. Thomas's questions today talking about the lack of value of clinical studies where there's not sufficient power. What does that mean, not sufficient power or number of patients?
A. You need a -- a big core of patients to be really sure that your findings are reliable and can be transferred to other patients or otherwise round.
Looking to ten patients for one week it will be likely result in non-significant differences. But you are not allowed to say that the -- the absent differences in this small cohort can be transferred to

the population in general, and therefore you need a -- or you can calculate the number of patients that are necessary to have a sufficient statistically power.

And roughly you need 1,500 patients in a group if you have an effect, let me say a reduction of a complication from ten to five percent. If you want to prove this difference you need at least 1,500 patients in a group, and you never -- I don't know any clinical study that can fulfill this. And it is ridiculous to believe that 80 patients are sufficient to give this certainty of finding.

Q. And after you account for the 22 percent lost to follow-up of 90 women, we're only talking about 60 women in this study that he's pointing to, correct?

A. That is correct, yeah.

Q. Is that enough, in your opinion, enough women to be able to look at and transfer whether or not this product will be safe in millions of other women?

MR. THOMAS: Object to the form of the question.

A. This study cannot serve -- should not serve as an argument for safety.

Q. And would it affect your opinions at all regarding the outcome of this study if you knew that the authors were paid $400,000 for every time they reported

no new complications on each one of the Nilsson studies? Would that affect your opinions at all?

MR. THOMAS: Object to the form of the question.

A. It raises some more concerns.

Q. I'll say.

You can strike that last comment.

Mr. Thomas also asked you a question about that study, saying they reported no shrinkage in these 60 women. He also showed you Klinge Exhibit 6 and Klinge Exhibit 7. One of them was where they looked at 70 women with some ultrasound on the vaginal tape and the other's where they looked at 94 patients and they put a Q-tip in their urethra to see whether or not those were shrunken. And do you remember those articles?

A. Yes.

Q. When is the best ability for you to look as to whether or not polypropylene mesh shrinks in the body, once you've removed it or while it's in the body?

MR. THOMAS: Object to the form of the question.

A. You can do it by both, by both ways. You can -- you can look to the width of the mesh within the body, but you can see as well -- you will recognize the shrinkage when looking at the explants.

Q. And for these studies, these meshes were still in the women, correct?

A. Yes.

Q. Okay. And if a sling has been removed from a woman due to complications as a result of contraction, and you can observe those on histology, correct?

A. Yes.

Q. In other words, looking under pathological slides.

A. Yes.

Q. Is looking at pathological slides of contracted heavyweight small-pore mesh like the PROLENE, and in fact looking at the PROLENE itself, something that you have done over the last 20 years?

MR. THOMAS: Object to the form of the question.

A. Yes, we -- we had the opportunity to look at various explants.

Q. Dozens, hundreds?

A. Dozens.

Q. Okay. Mr. Thomas also showed you this article by Dirk Wehye. You know Dirk Wehye.

A. Yes.

Q. Colleague of yours?

A. Colleague of mine.

Q. Also William Cobb. There was this article they did on minipigs. Do you remember him showing you this, Klinge Exhibit 9?

A. Yes.

Q. If you look under the highlights of the first page it says, "Large pore size greater than 1.5 millimeter leads to better integration and biomechanical capacity."

Do you agree with that?

A. Totally agree.

Q. Is that something that's been expressed in your opinions here today?

A. That is expressed in the opinions, and this is widely acknowledged and accepted in the literature.

Q. And on the second page of that it says, "A typical phenomenon of scar formation may cause the retraction of the mesh and it is proven in clinical studies that small pores, less than one millimeter, induce a connective tissue scar plate which is described as the bridging effect by Klinge and colleagues."

Do you agree with that statement?

A. I totally agree. No objection to it.

Q. And when they looked at these meshes here they were looking at -- were they looking at experimental meshes, in other words, not on the market, or ones that

were actually on the market?
A. No, they used only experimental meshes.
Q. So these are all protocol meshes that Covidien was looking at, correct?
A. Prototype just to -- to investigate the relationship of the impact factors.
Q. Two-dimensional, three-dimensional I think he pointed out to you, correct?
A. Yes.
Q. Is it true that if you -- if you design a mesh that has such low weight and such large pores that it could actually cause complications?
MR. THOMAS: Object to the form of the question.
A. Of course there is a critical limit. If you reduce the amount of material to almost zero, and expand the holes to giant dimensions, of course this will not work. And therefore I -- sometimes I said it is always a compromise. You have to define the necessary strength and the elasticity and then to try to find to get the safest design for this mechanical need.
Q. So can you take Klinge 9, this minipig study, and -- of experimental meshes that aren't on the market, and say large-pore heavyweight meshes -- I'm sorry -- large-pore lightweight meshes induce more shrinkage than

small-pore heavyweight meshes? Does it stand for that proposition?
A. No, it doesn't give any -- any safe data to -- to make this conclusion.
Q. Mr. Thomas asked you a lot of questions about your testing with Professor Muhl, and asked you whether or not if you changed the machine to 975 microns or 990 microns or 1,100 microns, whether or not this would somehow skew the results. Do you remember those questions?
A. Yes.
Q. Based upon your 20 years of research, your review of explanted meshes, your work with Ethicon as a consultant, your development of the new generation lightweight large-pore meshes, and all of the things you reviewed in this case, all of your publications and your speaking at conferences around the world, does it matter to you whether or not a mesh has 900 or a thousand microns before it goes into a patient as to whether or not that's going to safely integrate in a patient's tissues?
MR. THOMAS: Object to the form of the question.
A. No, it -- there is no -- it doesn't make any -- any sense to discuss whether the last figure is decisive

for the tissue reaction. The main goal of this is to predict the risk to get this scar bridging within the entire holes.
And of course there are, as we have seen, there are other confounders at the surface coating, as the area where it is implanted, they may affect or they may influence this bridging. However, this is an objective, reliable, reproducible method to get a figure which relates to the risk of a textile -- textile to create this bridging fibrosis, nothing more.
Q. Mr. Thomas asked you some questions and he said, you trimmed your hernia mesh with scissors when you were a surgeon. Do you remember he asked you that?
A. Yes.
Q. Okay. And then you said, yes, but we cut it outside the operative field. Do you remember that?
A. Yes.
Q. Are hernia meshes flat meshes?
A. Yes.
Q. Okay. And is there stretch on the flat mesh, in other words, forces being placed on it like there is on the sling?
MR. THOMAS: Object to the form of the question.
A. It is supposed that the hernia mesh is placed

in a tension-free condition, without any -- any -- any forces that are applied to the implant.
Q. And for any of the flat hernia meshes that you've implanted, do they have this curling, roping, fraying and particle loss that we've been looking at today with regard to the TVT sling?
MR. THOMAS: Object to the form of the question.
A. We never saw with a flat mesh this -- this extent of roping there. We have sometimes a folding when we - we cannot place it in a very flat manner there, but we never saw this -- this roping that we have seen with the PROLENE mesh.
Q. Mr. Thomas went through a series of questions and said, PVDF mesh from DynaMesh is heavier weight than polypropylene mesh, its effective porosity is similar. Do you remember those questions?
A. Yes.
Q. What is the difference between looking at the weight of a PVDF mesh and the porosity or the pore size of a PVDF mesh versus a comparison with a polypropylene mesh weight and a polypropylene mesh hole size? Can you explain that, please, and make it clear for the jury?
A. If you're just looking to the weight you don't have any information about the surface. You can -- when

Page 274

you have very, very thin fibers of either polymer you have a huge surface, a huge contact surface of the polymer with an awful tissue reaction therefore. Therefore, the weight, per se, is insufficient to predict the tissue response to it.

We know from all of our studies that when you are looking to the foreign body reaction to the thickness of the wall by the white blood cells and the scar reaction around the fiber, that the thickness of this reaction is significantly smaller than the size of this reaction in the neighborhood of polypropylene fibers.

Q. And what does that mean to the patient if you have less inflammation around the PVDF mesh and more inflammation around the polypropylene fibers?

A. With smaller holes you have not the high risk to create the bridging fibrosis if you are using the PVDF. So if using PVDF you are allowed to use smaller pores, then with the polypropylene in particularly if you have these thick fibers that are used in the PROLENE mesh.

Q. Then Mr. Thomas asked you, he said, have you done studies showing that particles shed or don't shed from the DynaMesh, etcetera. Do you remember those questions?

Page 275

A. Yes.

Q. When you did your published peer-reviewed studies and you compared the TVT PROLENE mesh to the DynaMesh sling and you put them under force, did the edges of the DynaMesh sling fray?

A. No, it is impossible, because the borders are sealed. So in this area it is -- you will not have any -- any particle loss.

Q. And when you put the force on the -- the various forces on the DynaMesh sling made out of PVDF, did those pores collapse? Did those holes collapse on themselves like the TVT did?

A. No, they are very, very resistant to the mechanical forces. They keep their structure and they -- they stay open.

Q. Did they curl like the TVT?

A. No.

Q. Did they rope like the TVT?

A. No.

Q. Mr. Thomas asked you a lot of questions about your relationship with FEG, and he said on cross-examination, Doctor, you got royalties on VYPRO, VYPRO II and ULTRAPRO from your work with Ethicon and your development with them on those meshes over 10 years. Do you remember that?

Page 276

A. Yes.

Q. Okay. While you were receiving royalties from the sales of -- by Ethicon of VYPRO, VYPRO II and ULTRAPRO, was that at the same time that you were telling Ethicon and FEG that you believed PVDF was a safer alternative to polypropylene?

MR. THOMAS: Object to the form of the question.

Q. Is that time period correct?

A. It is -- it is -- it started in 2000, and I got the royalties between 2000 and 2005, and we told 1998 to the people of Ethicon that we want to develop PVDF.

Q. So is it true that it was not in your financial interest to tell people that PVDF was better because you were actually getting royalties on a polypropylene mesh, correct?

MR. THOMAS: Object to the form of the question.

A. That is correct.

Q. Let's see.

MR. ANDERSON: We've covered minipigs to Q-tips. I think we're -- I think we're done. Go ahead.

RECROSS-EXAMINATION

BY MR. THOMAS:

Page 277

Q. Doctor -- do you have the mesh classification document there?

Doctor, if it's okay I'm going to sit next to you.

A. You're welcome.

Q. Thank you.

I'm going to show you again Klinge Exhibit No. 13, and you talked about the weight, relative weight of Marlex and PROLENE. Do you remember your questions about that?

A. Yes.

Q. And this is Table 1 of Exhibit No. 13 where you're comparing the brand names of different meshes, correct? And you pointed out that the Marlex was 95 grams and the PROLENE was 109 grams. We've already decided that the weight by itself is not important, correct? You've got to add other factors as well, correct?

A. Only in the situation where you have quite similar filaments made of a similar polymer. Then of course the difference in weight indicates that there is a difference in the amount of the material and a difference in surface. So in this, for this comparison, therefore for a long time we have been satisfied to just talk about the weight.

Q. But if you look at Marlex, PROLENE has a 50-percent higher textile porosity than Marlex, doesn't it?
A. That is how it is written there, yeah.
Q. So you understand that to be true, that the Marlex pore size is typically considered to be about .6 millimeters, isn't it?
A. Therefore, I pointed out that you have to look at the size of the filament. But if you change the size of the filament, you can create the difference.
Q. Is the answer yes, that Marlex -- that PROLENE has a 50-percent higher textile porosity over Marlex?
A. Yes.
Q. Which means that the Marlex pore size is typically reported as being about 6.6 millimeters, correct?
A. Point six millimeters, yeah.
Q. And the PROLENE is very close to one millimeter, correct?
A. It is reported like this. But you have to admit that these are the information mainly from the manufacturers and they are usually done by some methods with a lot of limitations. So it is a not so easy to reduce this to one thing.
Q. But Dr. Muhl's report, to be fair, shows that

the Ethicon PROLENE mesh is approximately one millimeter in all directions, with some minor variations.
A. If you're going to the report of Dr. Muhl it is quite clear how it is measured, what the limitations is. If you're going to these tables, it is very often not so indicated how these data are generated.
Q. But Dr. Muhl appropriately records those values, correct, as far as you know.
A. Yes.
Q. Okay. The Pariente study, Plaintiff's 1133, you were asked several questions about particle loss in the Pariente study. You didn't talk about how much load was applied to the meshes as a part of that study. Can you tell by looking at Plaintiff's Exhibit No. 33 how much load was applied to the TVT at the time they measured the particle loss there?
A. I'd have to look to the document as well.
Q. Please do.
A. I have to look to the -- to somewhere. A kilonewton is a thousand newton.
Q. Can you tell from the study how much force is being applied to the mesh?
A. You see here that on the left there is a --
MR. ANDERSON: He's trying to answer your question, Dave. That's what he's doing.

MR. THOMAS: I didn't say anything.
A. The YX is where you see the load, and it is .03 kilonewton, I guess.
Q. Do you know what the value of that is, what a kilonewton is?
A. It's a thousand, and they applied 30 newton to it. But I'm not sure.
Q. You're not able to tell from the study what kind of forces were applied to the TVT?
A. You can see in this figure how many force is applied, but I don't have it in my mind what is the dimension of kilonewtons and how to transfer it into simple newton. I have to look because it -- it's not a usually dimension where I'm working every day with kilonewton.
Q. Okay. Now, the documents that you were showed about the Kugel mesh and the Marlex refers to issues in hernia repair, don't they?
A. I was still there thinking, so I didn't get --
MR. ANDERSON: He's talking about a kilonewton.
Q. I only have a couple of these documents that Mr. Anderson showed you, 8064 and 8351, talking about a Heniford video clip and Dr. Schiaparelli. This all deals with the debate about the use of mesh in hernia repair, doesn't it?

A. It addresses the general aspect that there are -- that heavyweight and large-pore meshes have a higher risk. Whether they are thinking just of hernia and reducing it to hernia, I don't believe that they said that in other areas of the body that it's completely different. I've never heard it from them that they believe that the tissue reaction is different in other parts of the body.
Q. Would you hand me those stack of exhibits, please.
In the Colavita study, Trial Exhibit 3 Mr. Anderson asked you about, you said that there was nothing specifically in here about PROLENE mesh.
What a registry does is collect procedures for a period of time and then they're able to take the data that's developed during those procedures and group them in a manner that allows them to make scientific conclusions from the studies; fair?
A. That -- that is done during the process of analyzing and presenting the data.
Q. And that's -- while they didn't break out PROLENE hernia mesh, they did separate out lightweight mesh versus heavyweight mesh, correct? That's what we talked about in this study, correct?
A. They presented some data with these two groups

Page 282

of mesh materials. But you have to consider that they form a lot of these groups and now we're coming back again to the statistically power to this study, and it -- it decreases sharply when you're adding a lot of these subgroups there.

Q. But just to be clear, out of 710 repairs, when they looked at mesh weight, they concluded that mesh weight had no affect on pain, activity limitation, mesh sensation, overall symptoms, correct?

A. You read it correctly.

Q. Okay. And you talked about the Okulu study on redirect. I didn't get the number of that, Ben. Do you all have a number of that study?

MR. ANDERSON: PLT1085.

Q. 1085. And you suggest that these folks in Turkey had conducted a study where they used -- did they use -- they used ULTRAPRO mesh for the treatment of stress urinary incontinence, correct?

A. Yeah.

Q. Whatever the people in Turkey say, you don't want ULTRAPRO placed in your body, do you?

A. I think ULTRAPRO is a -- an excellent mesh in a tension-free condition. For small defects it is still one of the best or it has a very smooth tissue reaction because of these large pores. So I'm not sure whether

Page 283

it would be a bad choice in some indications to use ULTRAPRO.

Q. Okay. Let's go to your deposition, please, on October the 5th, 2015, just last month, on Page 90, Line 20. Let's turn to your report then on Page 36. Are you on Page 36 under -- I need a copy for the doctor.

MR. ANDERSON: Just read the deposition.

MR. THOMAS: Okay.

Q. Under -- this one right here, if you don't mind me helping him. You have it highlighted up here. You highlighted in your own copy of the deposition that you don't want the ULTRAPRO in your body, correct?

MR. ANDERSON: Excuse me. That's your copy of the deposition that you gave us for --

MR. THOMAS: This one is.

MR. ANDERSON: All of these are highlighted. These are the ones that you gave us before the deposition. So he didn't highlight it, you did.4.

THE WITNESS: In both versions it is highlighted.

MR. ANDERSON: I think we can stipulate to that.

MR. THOMAS: I apologize, Doctor, and I have some people to talk to.

Page 284

BY MR. THOMAS:

Q. Doctor, let's go back to Page 90, Line 16 -- Line 20, I'm sorry. Let's turn to your report then on Page 36, this is your Mullins' report. On Page 36 under safer alternative designs, one such safer alternative design would be a mesh product with less material, larger distance between the mesh fibers, and then you reference Ethicon's ULTRAPRO.

In prior depositions you've told me that ULTRAPRO was not an appropriate device for the treatment of stress urinary incontinence.

Are you suggesting now that it is an appropriate device for the treatment of stress urinary incontinence?

Answer: The ULTRAPRO in its present form or with these huge pores with these material reductions has, of course, advantages in comparison to the PROLENE material in regard to the tissue response.

And then you identify this Turkey study.

Then I say: Alternative for what?

For the PROLENE mesh, for stress urinary incontinence, and then you identify the Turkey study.

And then you say, however, on Page 92, Line 1, I know that ULTRAPRO has some disadvantages in regard to the structural stability and therefore I wouldn't like

Page 285

to have this in my body.

Did I read that correctly?

A. You read this correctly.

Q. Is that a true statement?

A. That the treatment has to be -- you have to differentiate in what form you want to have it. If you're using the ULTRAPRO to -- to serve as a ligament, as the PROLENE is intended to use, then you have the problem of the pore collapse. So the large-pore ULTRAPRO becomes a small-pore mesh device with all the risks.

If you use it like the Turkish people, and in fact at that time point I didn't have the idea that someone is using it in a different way. If you are using it to reenforce the tissues, as we did it with the flats meshes, then you don't have the risk for pore collapse, as with the ligaments, and with this procedure maybe it is a good idea to have it. But to use it as a ligament it's not a good idea, and as a ligament I don't want to have it.

Q. And you also, in response to questions from Mr. Anderson, referred to conversations you had with Ethicon about PVDF as a safer alternative design back in the time that you were working with the company. That was in the context of hernia repair, wasn't it? You

didn't work with the company on its SUI devices or its Prolift devices other than the conversation you've had with Dr. Hellhammer, correct?

MR. ANDERSON: Objection to the form of the question and the compound nature of it. Go ahead.

A. We never put the limitation to hernia out there ourselves, but it is a fact that we are just asked by Ethicon to work on hernia for them. But there -- to no time point we said that this is only true for hernia. Never.

Q. But the context of the work that you had with Ethicon and PVDF was in the context of hernia repair; true?

A. That is true. The project focused on hernia.

Q. And when you were talking about PVDF as an alternative mesh, it was in the context of hernia repair; true?

A. Not intentionally by ourselves that we said that this advantage is only true for hernia, no, never.

Q. But that's the context in which you had the conversations is in the context of hernia repair; true?

MR. ANDERSON: Objection. He's asked and answered your question a number of times. Answer it one more time, Dr. Klinge.

A. The project at that time, from the side of

Ethicon they were focused on hernia meshes. But the advantage, the discussions about the PVDF is not limited to hernia, and there is no data indicating that this is true only for hernia or for the abdominal wall, no.

Q. Move to strike everything after his first sentence.

MR. ANDERSON: Well, you shouldn't have asked him three times.

MR. THOMAS: I'm going to quit.

MR. ANDERSON: Okay. Just a few questions.

REDIRECT EXAMINATION (Continued)

BY MR. ANDERSON:

Q. Mr. Thomas was asking you questions about the pore size of Marlex being somewhere around .6 millimeters and the pore size of PROLENE at whatever millimeters he stated. Is there a difference between -- I want to clear this up for the jury one last time.

Is there a difference between talking about the pore size, or some measurement of the holes of the mesh by the manufacturer as it's coming out of the box, versus talking about what the holes do once it's in use by the surgeon and in the body?

So my question is, do these one millimeter pore size out of the box or .6 millimeters out of the box have any relationship to patient safety in how that mesh

and how those holes are going to incorporate in the tissue in the body?

MR. THOMAS: Object to the form of the question.

A. No, these data -- these data shouldn't be regarded as being relevant. The -- the relevant thing is whether you can see these fat within the pores and you see it neither with the Marlex nor with the PROLENE mesh, and therefore both -- it is correct to assume that both are heavyweight small-pore meshes with this high risk for fibrotic bridging.

And this creates this deformation we have shown by the scar formation, this contraction, this shrinking and this nerve entrapment by the scar. All of these complications are in relation to the extent of scar formation, and there is no significant difference in between what is said by the manufacturer or whether it's .6 or one millimeter. There is no difference in the quality of tissue reaction.

Q. Okay. He also was talking about kilonewtons and things like that from the Pariente study. Let me ask you this: When you and Professor Muhl, independently from Professor Moalli and her group at University of Pittsburgh, independently from Ethicon's own scientists, tested the TVT mechanical-cut mesh at

loads that Ethicon said could be anticipated in the body, was there significant particle loss that would affect your opinions as to whether or not that would be safe in the body?

MR. THOMAS: Object to the form of the question.

A. The mechanical cut leads to more particle loss than the laser cut.

Q. And was that determined after both your group, Moalli's group and Ethicon put forces that could be anticipated in the body?

A. Yes.

MR. THOMAS: Object to the form of the question.

Q. He also asked you a question, he showed you one study where there was a conclusion that said overall mesh weight had no effect on patient complications. Do you remember he showed that to you?

A. Yes.

Q. Did Ethicon change its hernia meshes to have much less weight in order to address patient complications starting in 1998?

MR. THOMAS: Object to the form of the question.

A. To my knowledge all of the meshes that has been

Page 290

developed since 1997, they were -- they had the design with a material reduction, they had the design with smaller filament size, they had the design with larger holes to reduce the risk operatively.

Q. And even though this one article had some conclusions that overall mesh weight didn't affect patient complications, did Ethicon utilize having much less material in their prolapse meshes that they put on the market since the middle of the 2000s?

MR. THOMAS: Object to the form of the question.

A. It is still used in the advertisements that it is a big advantage to have material reduction, to have larger holes, and this will improve the tissue reaction. This is still used for many of the products.

Q. And when you say advertisements, advertisements by Ethicon?

A. Yes.

MR. ANDERSON: No further questions.

MR. THOMAS: What's the last exhibit number?

MR. ANDERSON: Your last exhibit number? I don't know.

THE VIDEOGRAPHER: We are off the record at 5:57 p.m.

MR. THOMAS: Let's keep going. No, I'll do

Page 291

Exhibit 22, because there's no way we're near that, and we'll change it later if we have to.

RECROSS-EXAMINATION (Continued)

BY MR. THOMAS:

(Klinge Exhibit No. 22 was marked for identification.)

Q. Doctor, I've gone back to Dr. Muhl's report, and I'm attaching Pages 1, 2, 3, 4 and 5 of the image size of the TVT device zero force measurement. Are those the measurements that Dr. Muhl took of the TVT device at zero force? Are they?

MR. ANDERSON: Which figures are you talking about? There's like two pages full of figures.

A. It's written here, yes.

Q. What are they? Tell me what they are.

A. These images.

Q. And the measurements on the next page, next several pages, what do those represent? No, not the graph, but the numbers themselves.

A. This is an arbitrary way to get an impression about the distribution of the pores, because every textile construction have some sort of smaller pores and some sort of larger pores. And beyond the question whether it's sufficiently large or not sufficient large, that is the question for the effective porosity.

Page 292

We wanted to know what is the distribution, what is the relevance of a specific size of the pores. And you see, as you indicated already, that for the PROLENE mesh used in TVT, the pore size is around one millimeters or a little bit above. But, this pore size is just the square root of the area. That is not correct.

Because usually for the effective porosity you need the distance in all directions, and therefore the square root of the area is not very precisely. But it helps to get an understanding that you are close to the one millimeters in most of the pores.

But it is not -- it does not -- it is not able to -- to replace the definition of the effective porosity, because this considers the geometrical shape of the pores much more.

Q. And on Page 3 of Klinge 22 is a list of 119 detailed pore evaluations. And this is a measurement of each of the pores?

A. This is so far, I remember correctly, this is when you made an image analyze in here you get a huge variety of different areas, some bigger, some larger. And there you can take the square root and then you get different classes of -- of pores. Some are lower, some are a little bit larger. So then you can see in other

Page 293

textiles then that there is a considerably high number of small pores which may be ignored by just looking to the effective porosity.

Q. Okay. But these are Dr. Muhl's calculations of the pores that are present in the TVT PROLENE mesh device with a zero force measurement, correct?

A. Yes.

MR. THOMAS: That's all the questions I have.

MR. ANDERSON: Well, let's clear this up.

REDIRECT EXAMINATION (Continued)

BY MR. ANDERSON:

Q. It says millimeters squared on there, doesn't it, Doctor?

A. Yes.

Q. That is an area, not the distance between the fibers that you've talked about, correct?

A. Yes.

Q. So you could have a very, very long pore that is a half of a micron tall and 40 microns long. Will that be safe for bridging purposes?

A. No, definitely not.

Q. Can you use this document, as Mr. Thomas is trying to, to say that all these pores in the -- in the PROLENE mesh have one millimeter in all direction pore sizes?

A. These measurements does not allow to predict the risk for bridging, they just help to made a textile configuration.
Q. But, in fact, it doesn't even tell you whether or not they're one millimeter in diameter, does it?
A. No.
Q. It's just the square area, correct?
A. Yes.
MR. ANDERSON: Thank you.
RECROSS-EXAMINATION (Continued)
BY MR. THOMAS:
Q. The last entry does tell you the length of the main axis of the pore size, correct?
A. This is an arbitrary calculation on this.
Q. What do you mean arbitrary calculations? The numbers are different.
A. It is taken from the pore area.
Q. Okay. But it's an actual measurement of the pores that he measured as a part of this --
A. It's a calculation, it's not a measurement.
Q. Okay.
MR. THOMAS: Thank you. That's all I have.
REDIRECT EXAMINATION (Continued)
BY MR. ANDERSON:
Q. You can't take that -- we have to make this

clear. You can't take that piece of paper, as Mr. Thomas is trying to, and say that all of the pores in the TVT are one millimeter in diameter. You can't use it for that purpose, can you, Doctor?
A. No, you shouldn't do it, and it is impossible to take this information to explain that you don't have the bridging. You have the bridging, and this is in accordance to the measurement of the effective porosity, and not to these calculated data.
Q. And that's before any tension at all is placed on the mesh, correct?
A. Exactly.
MR. ANDERSON: Okay. No further questions.
MR. THOMAS: That's all. Thank you.
THE VIDEOGRAPHER: This concludes the deposition. We are off the record. The time is 6:03 p.m.
MR. ANDERSON: We need you as soon as humanly possible to get us the final.
MR. THOMAS: And I'll take the same.
(Signature having been waived, the deposition of DR. UWE KLINGE was concluded at 6:05 p.m.)

CERTIFICATE

I, TRINA B. WELLSLAGER, Registered Professional Reporter and Notary Public, do hereby certify that, pursuant to notice, the deposition of DR. UWE KLING was duly taken on 11/4/15 at 9:36 a.m. before me.
The said DR. UWE KLINGE was duly sworn by me according to law to tell the truth, the whole truth and nothing but the truth and thereupon did testify as set forth in the above transcript of testimony. The testimony was taken down stenographically by me. I do further certify that the above deposition is full, complete, and a true record of all the testimony given by the said witness.

_____
TRINA B. WELLSLAGER, RPR

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

LAWYER'S NOTES

PAGE	LINE	